DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 425, 455, and 495

[CMS–1752–P]

RIN 0938–AU44

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2022 and to implement certain recent legislation. In addition, we are proposing to rebase and revise the hospital market baskets for acute care hospitals, update the labor-related share, and provide the market basket update that would apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis, subject to these limits for FY 2022. We are also proposing policies relating to Medicare graduate medical education (GME) for teaching hospitals to implement certain recent legislation. The proposed rule would also update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2022. In this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to extend New COVID–19 Treatments Add-on Payment (NCTAP) for certain eligible products through the end of the fiscal year in which the PHE ends and to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022. We are also proposing to repeal the collection of market-based rate information on the Medicare cost report and the market-based MS–DRG relative weight methodology, as finalized in the FY 2021 IPPS/LTCH PPS final rule.

We are proposing to establish new requirements and revise existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Promoting Interoperability Program. We are also providing estimated and newly established performance standards for the Hospital Value-Based Purchasing (VBP) Program, and proposing updated policies for the Hospital Readmissions Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, Hospital VBP Program, Hospital-Acquired Condition (HAC) Reduction Program, and the PPS-Exempt Cancer Hospital Reporting (PCHQR) Program, and the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). Additionally, due to the impact of the COVID–19 PHE on measure data used in our value-based purchasing programs, we are proposing to suppress several measures in the Hospital VBP, HAC Reduction, and Hospital Readmissions Reduction Programs. In connection with our measure suppression proposals for the FY 2022 Hospital VBP Program, we are also proposing to revise the scoring and payment methodology for the FY 2022 program year such that hospitals will not be scored using quality measure data that are distorted by the effects of the COVID–19 public health emergency (PHE) and will not receive Total Performance Scores or adjustments to their payments as a result. Similarly, we are proposing to suppress affected measures for the FY 2022 HAC Reduction Program such that hospitals will not be scored using distorted quality measure data and will not receive Total HAC Scores based on those data. For the Hospital Readmissions Reduction Program, we are proposing to suppress one affected measure under the proposed measure suppression policy for the FY 2023 applicable period such that hospitals will not be assessed using distorted quality measure data and will not receive payment reductions based on those data.

In addition, we are proposing to change, clarify, and codify Medicare organ acquisition payment policies relative to organ procurement organizations (OPOs), transplant hospitals, and donor community hospitals. Also, we are proposing to add regulation requiring that state Medicaid agencies accept valid enrollments from all Medicare-enrolled providers and suppliers for purposes of processing claims for Medicare cost-sharing liability for services furnished to Medicare-Medicaid dually eligible individuals in order to alleviate a long-standing problem related to claiming Medicare bad debt.

Additionally, we are proposing to amend the Medicare Shared Savings Program regulations to allow eligible accountable care organizations (ACOs) participating in the BASIC track's glide path the opportunity to maintain their current level of participation for performance year (PY) 2022.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 28, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1752–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1752–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1752–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment

Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Critical Access Hospital (CAH) Issues.

Emily Lipkin, (410) 786–3633 and Jim Mildenberger, (410) 786–4551, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Emily Forrest, (202) 205–1922, Market-Based Data Collection and Market-Based MS–DRG Relative Weight Methodology Issues.

Allison Pompey, (410) 786–2348, New Technology Add On Payments and New COVID–19 Treatments Add-on Payments Issues.

Mady Hue, (410) 786–4510, and Andrea Hazeley, (410) 786–3543, MS–DRG Classifications Issues.

Mollie Knight, (410) 786–7948, and Bridget Dickensheets, (410) 786–8670, Rebasing and Revising the Hospital Market Baskets Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Pamela Brown, *pamela.brown@cms.hhs.gov*, Hospital Readmissions Reduction Program—Administration Issues.

Jim Poyer, *james.poyer@cms.hhs.gov*, Hospital Readmissions Reduction Program—Readmissions—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Administration Issues.

Yuling Li, (410) 786–8421, Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Administration Issues.

Katrina Hoadley, *katrina.hoadley@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing Programs—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Annie Hollis, *annie.hollis@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Katrina Hoadley, *katrina.hoadley@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting Program-Measure Issues.

Christy Hughes, (410) 786–5662, Long-Term Care Hospital Quality Reporting Program—Data Reporting Issues.

Jessica Warren, *jessica.warren@cms.hhs.gov*, Dylan Podson, *dylan.podson3@cms.hhs.gov*, and Elizabeth Holland, *elizabeth.holland@cms.hhs.gov*, Promoting Interoperability Programs.

Candace Anderson, (410) 786–1553, Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost-Sharing for Services Furnished to Dually Eligible Beneficiaries.

Katie Lucas, (410) 786–7723, Amanda Michael, (410) 786–5834, and Kellie Shannon (410) 786–0416, Organ Acquisition Payment Issues.

Naseem Tarmohamed, (410) 786–0814, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Shared Savings Program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov/*. Follow the search instructions on that website to view public comments.

Tables Available Through the Internet on the CMS Website

The IPPS tables for this FY 2022 proposed rule are available through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2022 IPPS Proposed rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2022 proposed rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1752–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2022 IPPS/LTCH PPS proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel at (410) 786–4552.

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2022 IPPS/LTCH PPS proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services

provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2022 proposed rule, we are continuing policies to address wage index disparities impacting low wage index hospitals; including a proposal to implement the imputed floor wage index provision of the American Rescue Plan Act of 2021; including proposals related to new technology add-on payments; and proposing to repeal the collection of market-based rate information on the Medicare cost report and the market-based MS–DRG relative weight methodology, as finalized in the FY 2021 IPPS/LTCH PPS final rule. This proposed rule also includes proposals to implement provisions of the Consolidated Appropriations Act of 2021 relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs.

We are proposing to establish new requirements and revise existing requirements for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

We are providing estimated and newly established performance standards for the Hospital Value-Based Purchasing (VBP) Program, and proposing updated policies for the Hospital Readmissions Reduction Program, Hospital Inpatient Quality Reporting (IQR) Program, Hospital VBP Program, Hospital-Acquired Condition (HAC) Reduction Program, Long Term Care Hospital Quality Reporting Program (LTCH QRP), and the PPS-Exempt Cancer Hospital Reporting (PCHQR) Program. Additionally, due to the impact of the COVID–19 PHE on measure data used in our value-based purchasing programs, we are proposing to suppress several measures in the Hospital VBP, HAC Reduction, and Hospital Readmissions Reduction Programs. As a result of these measure suppressions for the Hospital VBP Program we are also proposing a special scoring methodology for FY 2022 that results in a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG payment amount.

Under various statutory authorities, we either discuss continued program implementation or are proposing to make changes to the Medicare IPPS, to the LTCH PPS, other related payment methodologies and programs for FY 2022 and subsequent fiscal years, and other policies and provisions included in this rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated

care amount of all DSH hospitals expressed as a percentage.

- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by two percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1899 of the Act which established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers and suppliers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B.
- Section 1902(a)(23) of the Act, which specifies Medicaid provider enrollment requirements. States may set reasonable standards relating to the qualifications of providers but may not restrict the right of beneficiaries to obtain services from any person or entity that is both qualified and willing to furnish such services.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the proposed changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

a. Proposed MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110 90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2022, we are proposing to make an adjustment of +0.5 percent to the standardized amount.

b. Proposed Changes to the New COVID–19 Treatments Add-On Payment (NCTAP)

In response to the COVID–19 PHE, we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 and 71158). We believe that as drugs and biological products become available and are authorized for emergency use or approved by Food and Drug Administration (FDA) for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, CMS established the NCTAP.

We anticipate that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned MS–DRG may not adequately reflect the additional cost of new COVID–19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we believe that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (for example, until September 30, 2022). At the same time, we also believe that any new technology add-on payments that may be approved for a COVID–19 treatment would also serve to mitigate any potential financial disincentives for hospitals to provide that new COVID–19 treatment, such that the NCTAP would no longer be needed for that same product.

Therefore, we are proposing to extend NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends (for example, September 30, 2022). We also are proposing to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022.

c. Use of FY 2020 or FY 2019 Data in the FY 2022 IPPS and LTCH PPS Ratesetting

For the IPPS and LTCH PPS ratesetting, our longstanding goal is always to use the best available data overall. In section I.F. of the preamble of this proposed rule we discuss our analysis of the best available data for use in the development of this FY 2022 IPPS/LTCH PPS proposed rule given the potential impact of the public health emergency (PHE) for the Coronavirus Disease (COVID–19). As discussed in section I.F of the preamble of this proposed rule, we are proposing to use the FY 2019 data, such as the FY 2019 MedPAR file, for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE. In section I.O. of Appendix A of this proposed rule, we are also considering, as an alternative to this proposal, the use of the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, and which we may consider finalizing based on consideration of comments received.

d. Proposed Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low hospitals, in the FY 2020 IPPS/LTCH

PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, for FY 2022, we are continuing the low wage index hospital policy, and are also proposing to apply this policy in a budget neutral manner by applying an adjustment to the standardized amounts.

e. Proposed Implementation of Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) Imputed Floor Wage Index Policy for All-Urban States

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) amended section 1886(d)(3)(E) of the Act (42 U.S.C. 1395ww(d)(3)(E)) to establish a minimum area wage index for hospitals in all-urban States. Specifically, section 1886(d)(3)(E)(iv) of the Act (as added by section 9831(a)(2) of Pub. L. 117–2) reinstates the imputed floor wage index policy for all-urban states effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. Furthermore, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. We refer readers to section III.G.2. of this proposed rule for a summary of the provisions of section 9831 of Public Law 117–2 that we are proposing to implement in this proposed rule.

f. Proposed DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, FY 2014, Medicare DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2022. We are also proposing to continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2. Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule for FY 2022 and subsequent fiscal years, we are using a single year of data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports to calculate Factor 3 in the FY 2022 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. For IHS and Tribal hospitals and Puerto Rico hospitals we are proposing to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for FY 2022. We are proposing certain methodological changes for calculating Factor 3 for FY 2022.

Additionally, we are proposing to revise our regulation governing the calculation of the Medicaid fraction of the DSH calculation. Under this proposal, patient days of individuals receiving benefits under a section 1115 waiver program would be counted in the numerator of the Medicaid fraction only if the patient directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act.

g. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. In this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing the following policies: (1) To adopt a cross-program measure suppression policy; (2) to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) for the FY 2023 program year; (3) to modify the remaining five condition-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators, beginning with the FY 2023 program year; (4) to use the MedPAR data that aligns with the applicable period for FY 2022; (5) to automatically adopt the use of MedPAR data corresponding to the applicable period beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary; and (6) to update the regulatory text to reflect that our Hospital Compare website has been renamed and is now referred to as Care Compare. We are clarifying our Extraordinary Circumstances Exceptions (ECE) policy, and we are also requesting public comment on opportunities to advance health equity through possible future stratification of results by race and ethnicity for condition/procedure-specific readmission measures and by expansion of standardized data collection to additional social factors, such as language preference and disability status. We are also seeking comment on mechanisms of incorporating other demographic characteristics into analyses that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

h. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this proposed rule, we are proposing to: (1) Establish a measure suppression policy for the duration of the public health emergency for COVID–19; (2) suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Medicare Spending Per Beneficiary (MSPB), and five Healthcare-Associated Infection (HAI) measures, for the FY 2022 Program year; and (3) suppress the Hospital 30-Day,

All-Cause, Risk-Standardized Mortality Rate Following Pneumonia (PN) Hospitalization (MORT–30–PN) measure for the FY 2023 program year. We are also proposing to revise the scoring and payment methodology for the FY 2022 program year such that hospitals' Total Performance Scores will not include calculations based on these measures. We believe that awarding a TPS to any hospital based off the remaining measures that are not suppressed would not result in a fair national comparison and, as a result, are proposing not to award a TPS to any hospital for the FY 2022 program year. Instead, we are proposing to award each hospital a payment incentive multiplier that results in a value-based incentive payment that is equal to the amount withheld for the fiscal year (2 percent). We are proposing to remove the CMS Patient Safety and Adverse Events Composite (PSI 90) measure beginning with FY 2023 because the costs associated with the measure outweigh the benefit of its use in the program. We are also proposing to update the baseline periods for certain measures affected by the ECE granted in response to the COVID–19 PHE and to make a technical update to our terminology used in the Hospital VBP Program regulations.

i. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals, effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to hospitals that rank in the worst-performing quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to: (1) Clarify our ECE policy; (2) adopt a cross-program measure suppression policy; (3) apply that measure suppression policy to suppress certain program data; and (4) update the regulatory text to reflect that our *Hospital Compare* website has been renamed and is now referred to as *Care Compare.*

j. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year.

In this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to make several changes. We are proposing to adopt five new measures: (1) A new structural measure—Maternal Morbidity Structural Measure—beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 affecting the CY 2021 reporting period/FY 2023 payment determination; (2) the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure in a stepwise fashion, beginning with a voluntary reporting period from July 1, 2022 through June 30, 2023, and followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years; (3) the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination and with quarterly reporting beginning with the FY 2024 payment determination and for subsequent years; and two medication-related adverse event eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination; (4) Hospital Harm-Severe Hypoglycemia eCQM (NQF #3503e); and (5) Hospital Harm-Severe Hyperglycemia eCQM (NQF #3533e).

We are also proposing to remove five measures: (1) Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) beginning with the FY 2023 payment determination; (2) Exclusive Breast Milk Feeding (PC–05) (NQF #0480) beginning with the FY 2026 payment determination; (3) Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) (NQF #0497) beginning with the FY 2026 payment determination; and two stroke-related eCQMs beginning with the FY 2026 payment determination; (4) Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM (STK–03) (NQF #0436); and (5) Discharged on Statin Medication eCQM (STK–06) (NQF #0439).

We are requesting comment from stakeholders on the potential future development and inclusion of two measures: (1) A mortality measure for patients admitted with COVID–19; and (2) a patient-reported outcomes measure following elective total hip and/or total knee arthroplasty (THA/TKA). We are also requesting comment from stakeholders on ways we can leverage measures to address gaps in existing health equity generally as well as comment on: (1) Potential future confidential stratified reporting for the Hospital-Wide All-Cause Unplanned Readmission (HWR) measure using both dual eligibility and race/ethnicity; and (2) potential future reporting of a structural measure to assess the degree of hospital leadership engagement in health equity performance data. In this proposed rule, we are also requesting feedback across programs on potential actions and priority areas that would enable the continued transformation of our quality measurement toward greater digital capture of data and use of the FHIR standard.

In addition, beginning with the CY 2023 reporting period/FY 2025 payment determination, we are proposing to require hospitals to use certified technology that has been updated consistent with the 2015 Edition Cures Update and clarifying that certified technology must support the reporting requirements for all available eCQMs. We also are proposing that hybrid measures comply with the same certification requirements as eCQMs, specifically that EHR technology must be certified to the 2015 Edition Cures Update. We are proposing an update to revise 42 CFR 412.140(a)(2) and 42 CFR 412.140(e)(2)(iii) replacing the terms ''Security Administrator'' and ''System Administrator'' with the term ''security official'' in alignment with other CMS quality programs. Due to an updated URL for the QualityNet website from *QualityNet.org* to *QualityNet.cms.gov*, we are also proposing to revise Hospital IQR Program regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to reflect updates to the QualityNet website. Lastly, we are proposing to extend the effects of the educational review process for chart-abstracted measures beginning with validations affecting the FY 2024 payment determination.

k. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In this proposed rule, we are proposing to remove the Oncology: Plan of Care for Pain—Medical Oncology and

Radiation Oncology (NQF #0383) (PCH–15) measure beginning with the FY 2024 program year, adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel measure beginning with the FY 2023 program year, make a technical update to the terminology we use in the program, and codify existing PCHQR Program policies in our regulations.

l. Medicare Promoting Interoperability Program

For purposes of reducing the burden on eligible hospitals and CAHs, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) To continue the EHR reporting period of a minimum of any continuous 90-day period for new and returning eligible hospitals and CAHs for CY 2023 and to increase the EHR reporting period to a minimum of any continuous 180-day period for new and returning eligible hospitals and CAHs for CY 2024; (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from five points to 10 points for the EHR reporting period in CY 2022; (3) to modify the Provide Patient's Electronic Access to Their Health Information measure to establish a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, beginning with the EHR reporting period in CY 2022; (4) to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation, to the HIE objective as an optional alternative to the two existing measures beginning with the EHR reporting period in CY 2022; (5) to require reporting a ''yes'' on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting) or requesting the applicable exclusion(s); (6) adding a new measure to the Protect Patient Health Information objective that requires eligible hospitals and CAHs to attest to having completed an annual assessment of SAFER Guides beginning with the EHR reporting period in CY 2022; (7) to remove attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking requirement; (8) to increase the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) in order to be considered a meaningful EHR user; and (9) to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, in addition to removing four eCQMs from the measure set beginning with the reporting period in CY 2024 which is in alignment with the proposals for the Hospital IQR Program. We are amending our regulation texts as necessary to incorporate several of these proposed changes.

m. Proposed Repeal of Market-Based Data Collection and Market-Based MS–DRG Relative Weight Methodology

As discussed in section V.L. of the preamble of this proposed rule, we are proposing to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We are also proposing to repeal the market-based MS–DRG relative weight methodology adopted for calculating the MS–DRG relative weights effective in FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years. Lastly, we are soliciting comment on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) ratesetting. The proposed repeal of these policies would result in a reduction of 63,780 annual burden hours for all hospitals.

n. Proposed Implementation of Sections 126, 127 and 131 of the Consolidated Appropriations Act (CAA) of 2021

In this proposed rule, we are including proposals to implement sections 126, 127 and 131 of the Consolidated Appropriations Act (CAA) of 2021. Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) of the Act requiring the distribution of additional residency positions to qualifying hospitals. Section 127 of the CAA amended section 1886(h)(4)(H)(iv) of the Act to specify that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural track) in a rural area, the hospital, and each such hospital located in a rural area that participates in such a training, is allowed to receive an adjustment to its full-time equivalent (FTE) resident limit. Section 131 of the CAA amended section 1886(h)(2)(F) of the Act to provide an opportunity to hospitals with such extremely low or $0 per resident amounts (PRAs) that meet certain criteria to reset and establish new PRAs if the hospital trains resident(s) in a cost reporting period beginning on or after enactment [December 27, 2020] and before the date that is 5 years after enactment [December 26, 2025]. Section 131 also amended section 1886(h)(4)(H)(i) of the Act to provide an opportunity for hospitals that meet certain criteria and that have very small FTE resident caps to replace those caps if the Secretary determines the hospital begins training residents in a new program beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025). We refer readers to section V.J.2. of this proposed rule for rule for a summary of the provisions of sections 126, 127, and 131 of the CAA that we are proposing to implement in this proposed rule.

o. Proposed Changes to Organ Acquisition Payment Policy

In section X.B.2.h. of the preamble of this proposed rule, we are proposing to revise and codify the Medicare usable organ counting policy to count only organs transplanted into Medicare beneficiaries so that Medicare more accurately records and pays its share of organ acquisition costs.

p. Medicare Shared Savings Program

We are proposing to make changes to policies for the Shared Savings Program, which was established under section 1899 of the Act, to allow eligible ACOs participating in the BASIC track's glide path the option to elect to forgo automatic advancement along the glide path's increasing levels of risk and potential reward for performance year (PY) 2022. Under this proposal, prior to the automatic advancement for PY 2022, an eligible ACO may elect to remain in the same level of the BASIC track's glide path in which it participated during PY 2021. For PY 2023, an ACO that elects this advancement deferral option would be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if it had advanced automatically to the required level for PY 2022 (unless the ACO elects to advance more quickly before the start of PY 2023).

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, benefits associated with the major provisions described in section I.A.3. of the preamble of this proposed rule.

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Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Adjustment for MS-DRG Documentation and Coding Changes	Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2022, we are proposing to make an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.
Proposed Changes to the New COVID-19 Treatments Add-on Payment	In response to the COVID-19 PHE, CMS established the New COVID-19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID-19 cases that meet certain criteria (85 FR 71155). We anticipate inpatient cases of COVID-19 beyond the end of the PHE for which payment based on the assigned MS-DRG may not adequately reflect the additional cost of new COVID-19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we believe that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (for example, until September 30, 2022). At the same time, we also believe that any new technology add-on payments that may be approved for a COVID-19 treatment would also serve to mitigate any potential financial disincentives for hospitals to provide that new COVID-19 treatment, such that the NCTAP would no longer be needed for that same product. Therefore, we are proposing to extend the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends (for example, until September 30, 2022). We also are proposing to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022. On one extreme, if all of the new COVID–19 treatments decrease the net cost of hospitalizations (for example, due to shortened lengths of stay), including the cost of the new treatment, below the Medicare payment for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, then there would be no NCTAP made and no additional cost to the Medicare program as a result of this proposed extension. On the other extreme, if all of the new COVID–19 treatments result in the net cost of hospitalizations that exceed the outlier threshold (for example, due to the cost of the new treatment) for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, the cost to the Medicare program would be the sum over all such NCTAP cases of 0.65 times the outlier threshold for each case. Given it is unknown

Provision Description	Description of Costs, Transfers, Savings, and Benefits
	what the cost and utilization of inpatient stays using these new treatments will be, this proposal is a cost but is not estimable. Therefore, it is not possible to quantify the impact of the proposed extension of the NCTAP.
Proposed Implementation of Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) Imputed Floor Wage Index Policy for All-Urban States	As discussed in section III.G.2. of the preamble of this proposed rule, we are proposing to implement section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which reinstates the imputed floor wage index policy for all-urban states effective for discharges on or after October 1, 2021 (FY 2022) with no expiration date using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. Furthermore, section 1886(d)(3)(E)(iv)(III) of the Act (as added by section 9831(a)(2) of the American Rescue Plan Act of 2021) provides that the imputed floor wage index shall not be applied in a budget neutral manner. We estimate that our proposed implementation of section 9831 of the American Rescue Plan Act of 2021 would result in an estimated cost of approximately $0.2 billion for FY 2022.
Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care	For FY 2022, we are proposing to update our estimates of the three factors used to determine uncompensated care payments. We are proposing to continue to use uninsured estimates produced by OACT as part of the development of the NHEA in conjunction with more recently available data that takes into consideration the effects of the COVID-19 pandemic in the calculation of Factor 2. Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule for FY 2022 and subsequent fiscal years, we are using a single year of data on uncompensated care costs from Worksheet S–10 for FY 2018 to determine Factor 3 for FY 2022 for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. To determine the amount of uncompensated care for purposes of calculating Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are proposing to continue to use data regarding low-income insured days for FY 2013. We project that the amount available to distribute as payments for uncompensated care for FY 2022 will decrease by approximately $662 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2021. The uncompensated care payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges. Additionally, we are proposing to revise our regulation governing the calculation of the Medicaid fraction of the DSH calculation. Under this proposal, patient days of individuals receiving benefits under a section 1115 waiver program would be counted in the numerator of the Medicaid fraction only if the patient directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act. To the extent that this proposal has an impact on expenditures, that impact is not estimable because we do not have information on the number of section 1115 days by hospital which could be included in the Medicaid fraction absent the proposed revision to the regulation, which would be required to make an estimate.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, acute care hospitals are estimated to experience an increase of approximately $2.507 billion in FY 2022, including operating, capital, and new technology changes, as well as increased GME payments as a result of section 131 of the Consolidated Appropriations Act of 2021 and increased payments as a result of the imputed floor provision in section 9831 of the American Rescue Plan Act of 2021, as modeled for this proposed rule.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, based on the best available data for the 363 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present in the preamble of and Addendum to this proposed rule, which reflect the proposed update to the LTCH PPS standard Federal payment rate for FY 2022, would result in an estimated increase in payments in FY 2022 of approximately $52 million.
Proposed Changes to the Hospital Readmissions Reduction Program	For FY 2021 and subsequent years, DRG reductions in payments are based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. Overall, in this proposed rule, we estimate that 2,545 hospitals would have their base operating DRG payments reduced by their determined proxy FY 2022 hospital-specific readmission adjustment. As a result, we estimate that the Hospital Readmissions Reduction Program would save approximately $553 million in FY 2022.
Value-Based Incentive Payments under the Hospital VBP Program	We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2022 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2022 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2022 discharges is approximately $1.9 billion.
Proposed Changes to the HAC Reduction Program	A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year depend on several different factors. We are making no changes to the scoring methodology, which will continue to use the Winsorized z-score and equal measure weights approaches to determine the worst-performing quartile of hospitals. Any significant impact due to the HAC Reduction Program changes for FY 2022, including which hospitals will receive the adjustment, will depend on the actual experience of hospitals in the Program. For example, a hospital with poor performance during CY 2020 may move out of the worst-performing quartile status (that is, not receive a payment reduction) due to the proposed measure suppression policy. In turn, this would lead to another hospital moving into the worst-performing quartile status. In a typical year, approximately 18 percent of hospitals experience a change in worst-performing quartile status from one year to the next. Preliminary analysis indicates a reduction in the percentage of hospitals experiencing a change in worst-performing quartile status due to the proposed measure suppression policy. We refer readers to section IX.I.7.a.(3).c.
Proposed Changes to the Hospital Inpatient Quality Reporting (IQR) Program	Across 3,300 IPPS hospitals, we estimate that our proposed changes for the Hospital IQR Program in this proposed rule would result in a total information collection burden increase of 2,475 hours associated with our proposed policies and updated burden estimates and a total cost increase of approximately $101,475 across a 4-year period from the CY 2022 reporting period/FY 2024 payment determination through the CY 2025 reporting period/FY 2027 payment determination.
Changes to the Medicare and Promoting Interoperability Program	Based on updated wage rates for 2019 from the Bureau of Labor Statistics, and an amended hourly staff usage from that of a lawyer to a medical records and health information technician role, we estimate that the proposed changes would result in a decrease of $607,893 for the annual information collection burden (total cost) in CY 2022.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Implementation of Sections 126, 127, and 131 of the Consolidated Appropriations Act (CAA) of 2021	Section 1886(h) of the Act, as amended by sections 126, 127, and 131 of the CAA of 2021 (Pub. L. 116-260), provides for the distribution of additional residency positions (section 126), promotes a rural hospital GME funding opportunity (section 127), and requires resetting PRAs and FTE resident caps for certain hospitals after hosting medical resident rotators for short durations (section 131). We refer readers to section V.X.2. of this proposed rule for a summary of the provisions of sections 126, 127 and 131 that we are proposing to implement in this proposed rule. We estimate that the proposal that we present in the preamble of this proposed rule to implement section 126 of the CAA would result in an estimated cost of approximately $1.830 billion from FY 2023 through FY 2031. We estimate that the proposal that we present in the preamble of this proposed rule to implement section 127 of the CAA would result in an estimated cost of approximately $0.130 billion from FY 2024 through FY 2031. We estimate that the proposal that we present in the preamble of this proposed rule to implement section 131 of the CAA would result in an estimated cost of approximately $1.380 billion from FY 2022 through FY 2031.
Market-Based MS-DRG Relative Weight Policy – Proposed Repeal	In section V.L. of the preamble of this proposed rule, we are proposing to repeal the requirement that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021. We are also proposing to repeal the market-based MS-DRG relative weight methodology adopted for calculating the MS-DRG relative weights effective in FY 2024. We previously estimated total annual burden hours for this policy are as follows: 3,189 hospitals times 20 hours per hospital equals 63,780 annual burden hours and $4,315,993. Therefore, a repeal of this policy would result in a reduction of 63,780 annual burden hours for all hospitals. We refer readers to section XI.B.11. of the preamble of this proposed rule for further analysis of this assessment.
Proposed Changes to Organ Acquisition Payment Policy	In section X.B.2.h. of the preamble of this proposed rule, we are proposing to revise and codify the Medicare usable organ counting policy to count only organs transplanted into Medicare beneficiaries so that Medicare more accurately records and pays its share of organ acquisition costs. We estimate a cost savings to the Medicare trust fund of $230 million in FY 2022, $1.74 billion over 5 years, and $4.150 billion over 10 years. We refer readers to section X.B.2.h. for further analysis of this assessment.
Changes to the Medicare Shared Savings Program	In section I.H.12 of the Appendix A of this proposed rule, we describe the estimated impacts of our proposed changes to the Shared Savings Program to extend the flexibility for eligible ACOs to elect to "freeze" their participation level along the BASIC track's glide path for PY 2022. The net effect of offering this flexibility is estimated to be a $90 million reduction in Federal spending, with the reduction ranging from $50 to $140 million.

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B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual

updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation That Would Be Implemented in This Proposed Rule

1. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

2. Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

Sections 126, 127 and 131 of the Consolidated Appropriations Act, 2021 made a number of changes to various sections of the Act relating to payment for direct GME and IME costs to hospitals.

a. Section 126 of the Consolidated Appropriations Act, 2021

Section 126 amended section 1886(h) of the Act by adding a new section 1886(h)(9) requiring the distribution of additional residency positions to qualifying hospitals. Section 1886(h)(9)(A) requires that for FY 2023, and for each succeeding fiscal year until the aggregate number of full-time equivalent residency positions distributed is equal to 1,000, the Secretary shall initiate separate rounds of applications from hospitals for these additional residency positions. The Secretary is required, subject to certain provisions in the law, to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved by the Secretary for that hospital. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31 of the fiscal year of the increase, and the increase is effective beginning July 1 of that fiscal year. Section 1886(h)(9)(A) also limits the aggregate number of such positions made available in a single fiscal year across all hospitals to no more than 200.

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(9)(B) requires the Secretary to take into account the demonstrated likelihood of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(9)(B) of the Act also requires a minimum distribution for certain categories of hospitals. Specifically, the Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of hospitals. Stated briefly, and discussed in greater detail in later in this proposed rule, the categories are as follows: (1) Hospitals located in rural areas or that are treated as being located in a rural area; (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). Additionally, section 1886(h)(9)(F)(ii) of the Act defines a qualifying hospital as a hospital in one of these four categories.

Section 1886(h)(9)(C) of the Act places certain limitations on the distribution of the residency positions. First, a hospital may not receive more than 25 additional full-time equivalent residency positions. Second, no increase in the otherwise applicable resident limit of a hospital may be made unless the hospital agrees to increase the total number of full-time equivalent residency positions under the approved medical residency training program of the hospital by the number of positions made available to that hospital.

b. Section 127 of the Consolidated Appropriations Act, 2021

Section 127 of the CAA amended section 1886(h)(4)(H)(iv) of the Act to

specify that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, the hospital, and each such hospital located in a rural areas that participates in such a training, is allowed to receive an adjustment to its full-time equivalent (FTE) resident limit.

c. Sections 131 of the Consolidated Appropriations Act, 2021

Section 131 of the CAA amended section 1886(h)(2)(F) of the Act to provide an opportunity to hospitals with such extremely low or $0 per resident amounts (PRAs) that meet certain criteria to reset and establish new PRAs if the hospital trains resident(s) in a cost reporting period beginning on or after enactment [December 27, 2020] and before the date that is 5 years after enactment [December 26, 2025]. Section 131 of the CAA also amended section 1886(h)(4)(H)(i) of the Act to provide an opportunity for hospitals that meet certain criteria and that have very small FTE resident caps to replace those caps if the Secretary determines the hospital begins training residents in a program year beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025).

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2022 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2022.

The following is a general summary of the changes that we are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2022.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2022 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2022 status of new technologies approved for add-on payments for FY 2022, a presentation of our evaluation and analysis of the FY 2022 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Public Law 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2022 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- A proposal to extend the New COVID–19 Treatments Add-on Payment (NCTAP) through the end of the fiscal year in which the PHE ends for certain products and discontinue NCTAP for products approved for new technology add-on payments in FY 2022.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of this proposed rule we are proposing to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but were not limited to, the following:

- The proposed FY 2022 wage index update using wage data from cost reporting periods beginning in FY 2018.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2022 based on the 2019 Occupational Mix Survey.
- Proposed application of the rural floor and the frontier State floor, and continuation of the low wage index hospital policy.
- Proposed implementation of the imputed floor wage index policy for all-urban states under section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2).
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed revisions to the regulations at § 412.278 regarding the Administrator's Review of MGCRB decisions.
- Proposed changes to rural reclassification cancellation requirements at § 412.103(g).
- Proposed adjustment to the wage index for acute care hospitals for FY 2022 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the proposed FY 2022 wage index.

3. Proposed Rebasing and Revising of the Hospital Market Baskets

In section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the hospital market baskets for acute care hospitals and update the labor-related share.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital update for FY 2022.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- The statutorily required IME adjustment factor for FY 2022.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed requirements for payment adjustments under the Hospital Readmissions Reduction Program for FY 2022.
- The provision of estimated and newly established performance standards for the calculation of value-based incentive payments, as well as a proposal to suppress multiple measures and provide net-neutral payment adjustments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2022.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2022.
- Proposed revisions to the regulations regarding the counting of days associated with section 1115 demonstration projects in the Medicaid fraction.
- Proposals to implement provisions of the Consolidated Appropriations Act relating to payments to hospitals for direct graduate medical education (GME) and indirect medical education (IME) costs.
- Proposed repeal of the market-based data collection requirement and market-based MS–DRG relative weight methodology.

5. Proposed FY 2022 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2022.

6. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of this proposed rule, we discuss—

- Proposed changes to payments to certain excluded hospitals for FY 2022.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

7. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of this proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2022.

8. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of this proposed rule, we address the following:

- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- Proposed changes to the requirements under the LTCH Quality Reporting Program (QRP). We are also seeking information on CMS's future plans to define digital quality measures (dQMs) for the LTCH QRP and on CMS' continued efforts to close the health equity gap.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

9. Other Proposals Included in This Proposed Rule

Section X. of the preamble to this proposed rule includes the following proposals:

- Proposed changes pertaining to Medicaid enrollment of Medicare-enrolled providers and suppliers to 42 CFR part 455.410 and request for comment on provider experiences where state Medicaid agencies apply the Medicaid payment and coverage rules to a claim for a Medicare service rather than adjudicating the claim for Medicare cost-sharing liability.
- Proposed changes pertaining to Medicare's share of organ acquisition costs transplanted into Medicare beneficiaries and the charges for services provided to cadaveric organ donors by donor community hospitals and transplants hospitals.
- Proposed changes pertaining to the Shared Savings Program that would allow eligible ACOs participating in the BASIC track's glide path to maintain their current level of participation for PY 2022.

10. Other Provisions of This Proposed Rule

Section XI. of the preamble to this proposed rule includes our discussion of the MedPAC Recommendations.

Section XII. of the preamble to this proposed rule includes the following:

- A descriptive listing of the public use files associated with the proposed rule.
- The collection of information requirements for entities based on our proposals.
- Information regarding our responses to public comments.

11. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to this proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2022 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to this proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2022 for certain hospitals excluded from the IPPS.

12. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2022 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2022. We are proposing to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

13. Impact Analysis

In Appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs and other entities.

14. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2022 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

15. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2021 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2021 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at: *http://www.medpac.gov*.

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health

Information Technology (ONC) participate inin the Post-Acute Care Interoperability Workgroup (PACIO *http://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop FHIR standards. These standards could support the exchange and reuse of patient assessment data derived from the Minimum Data Set (MDS), Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), LTCH Continuity Assessment Record and Evaluation (CARE Data Set (LCDS), Outcome and Assessment Information Set (OASIS), and other sources. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech language pathology. We encourage post-acute care (PAC) provider and health information technology (IT) vendor participation as the efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards, such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED). The DEL furthers CMS' goal of data standardization and interoperability. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision-making. Standards in the Data Element Library (*https://del.cms.gov/DELWeb/pubHome*)can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at *https://www.healthit.gov/isa*.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision [1] that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement* and *https://rce.sequoiaproject.org/*.

The ONC final rule entitled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (85 FR 25642) published in the May 1, 2020 **Federal Register**, (hereinafter referred to as ''ONC Cures Act Final Rule'') implemented policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the HHS Secretary as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information. For a health care provider (as defined in 45 CFR 171.102), the definition of information blocking (see 45 CFR 171.103) specifies that the provider knows that the practice is unreasonable, as well as likely to interfere with access, exchange, or use of electronic health information.[2] To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers need to be established by the Secretary through rulemaking. Stakeholders can learn more about information blocking at *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking*. ONC has posted information resources including fact sheets (*https://www.healthit.gov/curesrule/resources/fact-sheets*), frequently asked questions (*https://www.healthit.gov/curesrule/resources/information-blocking-faqs*), and recorded webinars (*https://www.healthit.gov/curesrule/resources/webinars*).

We invite providers to learn more about these important developments and how they are likely to affect LTCHs.

F. Use of FY 2020 or FY 2019 Data in the FY 2022 IPPS and LTCH PPS Ratesetting

We primarily use two data sources in the IPPS and LTCH PPS ratesetting: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available MedPAR data would be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. For FY 2022 ratesetting, under ordinary circumstances, the best available data would be the FY 2020 MedPAR file. The cost report data source is the Medicare hospital cost report data files from the most recent quarterly HCRIS release. For example, ordinarily, the best available cost report data used in relative weight calculations would be based on the cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking. For the FY 2022 ratesetting, under ordinary circumstances, that would be the FY 2019 cost report data from HCRIS, which would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.

The FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset both contain data significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE, as we discuss in this section. Accordingly, we question whether these data sources are the best available data to use for the FY 2022 ratesetting. One factor in assessing whether these data sources represent the best available data is to what extent the FY 2019 data from before the COVID–19 PHE is a better overall approximation of FY 2022 inpatient experience (for example, whether the share of total inpatient utilization for elective surgeries will be more similar to FY 2019 than to FY 2020), or alternatively, to what extent the FY 2020 data which include the COVID–19 PHE time period is a better overall approximation of FY 2022 inpatient experience (for example, whether the share of total inpatient utilization for respiratory infections will be more similar to FY 2020 than to FY

[1] ONC, *Draft 2 Trusted Exchange Framework and Common Agreement, https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf*.

[2] For other types of actors (health IT developers of certified health IT and health information network or health information exchange, as defined in 45 CFR 171.102), the definition of ''information blocking'' (see 45 CFR 171.103) specifies that the actor ''knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information.''

2019). Another factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 IPPS ratesetting.

In order to help assess likely inpatient utilization in FY 2022, we examined the trend in the number of COVID–19 vaccinations in the United States as reported to the Centers for Disease Control (CDC) (see *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html*, accessed April 16, 2021).

The U.S. COVID–19 Vaccination Program began December 14, 2020. As of April 15, 2021, 198.3 million vaccine doses have been administered. Overall, about 125.8 million people, or 37.9 percent of the U.S. population, have received at least one dose of vaccine as of this date. About 78.5 million people, or 23.6 percent of the U.S. population have been fully vaccinated.[3] As of April 15, the 7-day average number of administered vaccine doses reported to CDC per day was 3.3 million, a 10.3 percent increase from the previous week. As of April 15, 80 percent of people 65 or older have received at least one dose of vaccine; 63.7 percent are fully vaccinated. Nearly one-half (48.3 percent) of people 18 or older have received at least one dose of vaccine; 30.3 percent are fully vaccinated. Nationally, COVID–19-related emergency department visits as well as both hospital admissions and current hospitalizations have risen among patients ages 18 to 64 years in recent weeks, but emergency department visits and hospitalizations among people ages 65 years and older have decreased, likely demonstrating the important role vaccination plays in protecting against COVID–19.

As indicated by the CDC, COVID–19 vaccines are effective at preventing COVID–19.[4] For example, a recent CDC report on the effectiveness of the Pfizer-BioNTech and Moderna COVID–19 vaccines when administered in real-world conditions found that after being fully vaccinated with either of these vaccines a person's risk of infection is reduced by up to 90 percent. With respect to inpatient utilization in FY 2020, we believe that COVID–19 and the risk of disease were drivers of the different utilization patterns observed. Therefore, the continuing rapid increase in vaccinations coupled with the overall effectiveness of the vaccines leads us to conclude based on the information available to us at this time that there will be significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. This calls into question the applicability of inpatient data from FY 2020 to the FY 2022 time period for hospitals paid under the IPPS and LTCH PPS.

We also reviewed CDC guidance to healthcare facilities during the COVID–19 PHE (see *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html*). In its most recent guidance, the CDC described how the COVID–19 pandemic has changed how health care is delivered in the United States and has affected the operations of healthcare facilities. Effects cited by the CDC include increases in patients seeking care for respiratory illnesses, patients deferring and delaying non-COVID–19 care, disruptions in supply chains, fluctuations in facilities' occupancy, absenteeism among staff because of illness or caregiving responsibilities, and increases in mental health concerns.

In order to investigate the effects cited by the CDC, we examined the claims data from the FY 2020 MedPAR compared to the FY 2019 MedPAR. Overall, in FY 2020, inpatient admissions under the IPPS dropped by approximately 14 percent compared to FY 2019. Elective surgeries declined significantly, and the share of admissions for MS–DRGs associated with the treatment of COVID–19 increased. For example, the number of inpatient admissions for MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) dropped by 40 percent in FY 2020. Its share of inpatient admissions dropped from 4.0 percent in FY 2019 to 2.8 percent in FY 2020. The number of inpatient admissions for MS–DRG 177 (Respiratory Infections and Inflammations with MCC) increased by +133 percent. Its share of inpatient admissions increased from 0.8 percent in FY 2019 to 2.2 percent in FY 2020. This data analysis is consistent with the observations in the CDC's guidance that COVID–19 increased the number of patients seeking care for respiratory illnesses, and caused patients to defer and delay non-COVID–19 care. We note that these observed changes in the claims data also extend to the cost reports submitted by hospitals that include the COVID–19 PHE time period, since those cost reports that extend into the COVID–19 PHE are based in part on the discharges that occurred during that time.

The effects noted by the CDC are specific to the pandemic and to the extent that the effects on healthcare facilities noted by the CDC are not expected to continue into FY 2022, it would suggest that the inpatient data from FY 2020 impacted by the COVID–19 PHE may be less suitable for use in the FY 2022 ratesetting.

We also considered the analysis of 2020 IPPS real case-mix included in the notice titled ''CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts'' that appeared in the **Federal Register** on November 12, 2020 (85 FR 71916). Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by the best estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates to hospitals, and adjusted to reflect changes in real case-mix.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflected the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the IPPS in FY 2020 compared to FY 2019, using Medicare bills from IPPS hospitals received as of July 2020. Those bills represented a total of about 6.1 million Medicare discharges for FY 2020 and provided the most recent case-mix data available at the time of that analysis. Based on these bills, the change in average case-mix in FY 2020 was 2.8 percent. Based on these bills and past experience, we expected the overall case-mix change to be 3.8 percent as the year progressed and more FY 2020 data became available.

Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. As stated in the November 2020 notice, COVID–19 has complicated the determination of real case-mix increase. COVID–19 cases typically group to higher-weighted MS–DRGs, and hospitals have experienced a concurrent reduction in cases that group

[3] People who are fully vaccinated (formerly receiving 2 doses) represents the number of people who have received the second dose in a two-dose COVID–19 vaccine series or one dose of the single-dose J&J/Janssen COVID–19 vaccine.

[4] Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA–1273 COVID–19 Vaccines in Preventing SARS–CoV–2 Infection Among Health Care Personnel, First Responders, and Other Essential and Frontline Workers—Eight U.S. Locations, December 2020–March 2021, available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_e&ACSTrackingID=USCDC_921-DM53321&ACSTrackingLabel=MMWR%20Early%20Release%20-%20Vol.%2070%2C%20March%2029%2C%202021&deliveryName=USCDC_921-DM53321*, accessed April 2, 2021).

to lower weighted MS–DRGs. Both of these factors cause a real increase in case-mix. We compared the average case-mix for February 2020 through July 2020 (COVID–19 period) with average case-mix for October 2019 through January 2020 (pre-COVID–19 period). Since this increase applies for only a portion of CY 2020, we allocated this increase by the estimated discharges over the 2 periods—a 2.5 percent increase for FY 2020. The 1.3-percent residual case-mix increase is a mixture of real case-mix and coding optimization. Over the past several years, we have observed total case-mix increases of about 0.5 percent per year and have assumed that they are real. Thus, based on the information available, we expect that 0.5 percent of the residual 1.3 percent change in average case-mix for FY 2020 will be real. The combination of the 2.5 percent COVID–19 effect and the remaining residual 0.5-percent real case-mix increase results in an estimated 3.0 percent increase in real case-mix for FY 2020.

Because this analysis was based on Medicare bills from IPPS hospitals received as of July 2020, for this proposed rule, we calculated case-mix values for FY 2019 and FY 2020 based on the full year FY 2019 and FY 2020 MedPAR files to help assess the change in case-mix based on more complete data. For FY 2019 we calculated a case-mix value of 1.813 and for FY 2020 we calculated a case-mix value of 1.883, an increase in total case-mix of 3.9 percent. These were calculated using the MS–DRG relative weights in effect for those time periods.[5] This is consistent with the estimate in the Notice of the CY 2021 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts that the change in total case-mix for FY 2020 would be 3.8 percent when more complete data was available.

The increases in patients seeking care for respiratory illnesses and patients deferring and delaying non-COVID–19 care during FY 2020, the increasing number of vaccinations for COVID–19, and the high estimate of FY 2020 real case-mix growth all lead us to believe that FY 2020 is not the best overall approximation of inpatient experience in FY 2022. We believe that FY 2019 as the most recent complete FY prior to the COVID–19 PHE is a better approximation of FY 2022 inpatient experience.

As we indicated earlier, whether the data is a better overall approximation of FY 2022 inpatient experience is one factor in assessing which data source represents the best available data for the FY 2022 rulemaking. Another factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 ratesetting. One way to assess this factor is to model the change in the total case-mix, which is a driver of spending, if our assumption regarding the FY 2022 inpatient experience used in calculating the MS–DRG relative weights turns out to be less accurate based on actual FY 2022 experience. We estimated the difference in the total case-mix if we calculated the MS–DRG relative weights based on the FY 2019 claims data and the actual utilization is ultimately more similar to the FY 2020 data, as compared to if we calculated the MS–DRG relative weights based on the FY 2020 data and the actual utilization is ultimately more similar to the FY 2019 data.

We first calculated a set of MS–DRG relative weights using an assumption that the FY 2022 inpatient experience would be similar to the FY 2019 data. Specifically, we used the proposed version 39 GROUPER (which would be applicable to discharges occurring in FY 2022) and the FY 2019 MedPAR data to calculate MS–DRG relative weights. We refer to these MS–DRG relative weights as the FY 2019-based weights.

We next calculated a set of MS–DRG relative weights using an assumption that the FY 2022 inpatient experience would be more similar to the FY 2020 data. Specifically, we used the proposed version 39 GROUPER and the FY 2020 MedPAR data to calculate MS–DRG relative weights. This is how we would ordinarily calculate the proposed FY 2022 MS–DRG relative weights. We refer to these MS–DRG relative weights as the FY 2020-based weights.

We then estimated the difference in case-mix under the FY 2019-based weights and the FY 2020-based weights if the FY 2022 inpatient experience ended up being the reverse of the assumption made when calculating that set of relative weights. In other words, we compared estimated case-mix calculated under four different scenarios. For the FY 2019-based weights, we calculated the case-mix using claims from the FY 2019 MedPAR as an approximation of the actual FY 2022 experience (Scenario A), and using claims from the FY 2020 MedPAR as an approximation of the actual FY 2022 experience (Scenario B). For the FY 2020-based weights, we calculated the case-mix using claims from the FY 2020 MedPAR as an approximation of the actual FY 2022 experience (Scenario C), and using claims from the FY 2019 MedPAR as an approximation of the actual FY 2022 experience (Scenario D).

The results are shown in the following table.

Scenario	Assumed FY 2022 Experience for Relative Weights	Actual FY 2022 Experience	Case-mix	Assumption Matched Experience?	Percent Change in Case-mix if Mismatch between Assumption and Actual Experience
A	FY 2019	FY 2019	1.820	Yes	
B	FY 2019	FY 2020	1.885	No	0.0%
C	FY 2020	FY 2020	1.885	Yes	
D	FY 2020	FY 2019	1.816	No	-0.2%

[5] Section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act directs the Secretary of HHS to increase the weighting factor of the assigned DRG by 20 percent for an individual diagnosed with COVID–19 discharged during the COVID–19 PHE period. In order to make the case-mix values more comparable, the 20 percent increase is not included.

In Scenario A and Scenario C, there is by definition no differential impact on total case-mix due to a less accurate assumption made when the MS–DRG relative weights were calculated: The FY 2022 inpatient experience matches the assumption used when the MS–DRG relative weights were calculated. In Scenario B and Scenario D, it is the reverse of the assumption used when the MS–DRG relative weights were calculated.

In Scenario B, when the FY 2019-based weights were used, but the FY 2022 inpatient experience turns out to be more similar to FY 2020 data, the less accurate assumption does not differentially impact the modelled case-mix. This can be seen by comparing the modelled case-mix under Scenario B (1.885) with the modelled case-mix under Scenario C (also 1.885). In other words, if the FY 2019-based weights and inpatient experience turn out to be more similar to the FY 2020 data, then the modelled case-mix is approximately the same as if we had used the FY 2020-based weights. The results show that use of the FY 2019-based weights did not impact the modelled case-mix compared to using the FY 2020-based weights.

The same conclusion is not true of Scenario D where the FY 2020-based weights were used, but the FY 2022 inpatient experience turns out to be more similar to FY 2019 data. Here the less accurate assumption does differentially impact the modelled case-mix, by −0.2 percent. This can be seen by comparing the modelled case-mix under Scenario D (1.816) with the modelled case-mix under Scenario A (1.820). In other words, if we use the FY 2020-based weights, and FY 2022 inpatient experience turns out to be more similar to FY 2019 data, the modelled case-mix is −0.2 percent lower than if we had used the FY 2019-based weights. This shows that use of the FY 2020-based weights does impact the modelled case-mix compared to a result from using the FY 2019-based weights.

Putting aside that we believe FY 2019 is a more likely approximation of the FY 2022 inpatient experience for the reasons discussed earlier, the previous analysis indicates that the differential effect of the FY 2022 MS–DRG relative weights is more limited if the FY 2019-based weights are used than it is if the FY 2020-based weights are used, should the FY 2022 inpatient experience not match the assumption used to calculate the MS–DRG relative weights.

Another payment factor that is impacted by the use of the FY 2019 or FY 2020 data in the FY 2022 ratesetting is the outlier fixed-loss threshold. As discussed in section II.A.4.j. of this proposed rule, section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of certain payments and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments. We target 5.1 percent within this range. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. In other words, outlier payments are prospectively estimated to be budget neutral overall under the IPPS.[6]

Under an assumption that the FY 2022 inpatient experience will be more similar to FY 2019 data, we estimate an outlier fixed-loss amount of $30,967. Under an assumption that FY 2022 inpatient experience will be more similar to FY 2020 data, we estimate an outlier fixed-loss amount of $36,843, a difference of $5,876 or approximately 20 percent higher. Again, putting aside that we believe FY 2019 is a better approximation of the FY 2022 inpatient experience for the reasons discussed earlier, the difference between the two estimated outlier fixed-loss amounts means there is a consequence to making a decision as to the best available data for estimating the FY 2022 outlier fixed-loss amount in the form of potentially exceeding or falling short of the targeted 5.1 percent of total operating DRG payments plus outlier payments.

In summary, we have highlighted two factors in the decision regarding the best available data to use in the FY 2022 ratesetting. The first factor is to what extent the FY 2019 data from before the COVID–19 PHE is a better overall approximation of FY 2022 inpatient experience, or alternatively, to what extent the FY 2020 data including the COVID–19 PHE time period is a better overall approximation of FY 2022 inpatient experience. After analyzing this issue and for the reasons discussed, we believe for purposes of this proposed rule that FY 2019 is generally a better overall approximation of FY 2022. The second factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 IPPS ratesetting. After analyzing this issue, and as discussed previously, we have determined that the decision does differentially impact the overall FY 2022 IPPS ratesetting in two primary ways. First, a decision to base the MS–DRG relative weights on the FY 2020 data has an impact of −0.2 percent if the FY 2022 inpatient experience is more like FY 2019 data. Second, the decision to use the FY 2019 or FY 2020 data results in an approximately 20 percent difference in the estimate of the outlier fixed-loss amount.

Taking these factors into account, we are proposing to use the FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE, primarily in that the data reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE, as discussed previously. For example, we are proposing to use the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, such as in our analysis of changes to MS–DRG classifications (as discussed in greater detail section II.D. of the preamble of this proposed rule). Similarly, we are proposing to use cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file, such as in determining the proposed FY 2022 IPPS MS–DRG relative weights (as discussed in greater detail section II.E. of the preamble of this proposed rule). (As noted previously, the FY 2019 HCRIS data would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.) We note that MedPAR claims data and cost report data from the HCRIS file are examples of the data sources for which we discuss the proposed use of the FY 2019 data for the FY 2022 ratesetting in this proposed rule. We have clearly identified throughout this proposed rule where and how we are proposing to use alternative data than what ordinarily would be used for the proposed FY 2022 IPPS and LTCH PPS ratesetting, including certain provider specific information.

As discussed in section I.O. of Appendix A of this proposed rule, we are also considering, as an alternative to this proposal, the use of the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, and

[6] More information on outlier payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-forService-Payment/AcuteInpatientPPS/outlier.html.*

which we may consider finalizing based on consideration of comments received. To facilitate comment on this alternative for FY 2022, we are making available the FY 2020 MedPAR file and the FY 2019 HCRIS file that we would ordinarily have provided in conjunction with this proposed rule. We are also making available the MS–DRG and MS–LTC–DRG relative weighting factors and length of stay information calculated using the FY 2020 data we would have ordinarily used. We are providing a file comparing the budget neutrality and other ratesetting adjustments calculated under our proposal with those adjustments calculated under this alternative approach. Finally, we are making available other proposed rule supporting data files based on the use of the FY 2020 data that we ordinarily would have provided, including: The IPPS and LTCH PPS Impact Files; the AOR/BOR File; the Case Mix Index File; and, the Standardizing File. We refer the reader to section I.O. of Appendix A of this proposed rule for more information on where these supplemental files may be found.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2021 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, 83 FR 41158 through 41258, 84 FR 42058 through 42165, and 85 FR 58445 through 58596 respectively).

C. Proposed FY 2022 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FYs 2018, 2019, 2020 and 2021 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444–58445), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019, FY 2020, and FY 2021, respectively. We indicated the FY 2018, FY 2019, FY 2020, and FY 2021 adjustments were permanent adjustments to payment rates. We also stated that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2022 and 2023 in future rulemaking.

3. Proposed Adjustment for FY 2022

Consistent with the requirements of section 414 of the MACRA, we are proposing to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2022. This would constitute a permanent adjustment to payment rates. We plan to propose the final adjustment required under section 414 of the MACRA for FY 2023 in future rulemaking.

D. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2022 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for Proposed FY 2022 MS–DRG Updates

Given the need for more time to carefully evaluate requests and propose updates, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), we changed the deadline to request updates to the MS–DRGs to November 1 of each year, which provided an additional five weeks for the data analysis and review process. In the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32472), we stated that with the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and in order to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. We further stated we were changing the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. However, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58445), due to the unique circumstances for the FY 2021 IPPS/LTCH PPS final rule for which we waived the delayed effective date, we maintained the deadline of November 1, 2020 for FY 2022 MS–DRG classification change requests. We also noted that we expected to reconsider a change in the deadline beginning with comments and suggestions submitted for FY 2023. While we continue to believe that a change in the deadline from November 1 to October 20 will provide hospitals sufficient time to assess potential impacts and inform future MS–DRG recommendations, we are maintaining the deadline of November 1 for FY 2023 MS–DRG classification change requests.

As noted, interested parties had to submit MS–DRG classification change requests for FY 2022 by November 1, 2020, and the comments that were submitted in a timely manner for FY 2022 are discussed in this section of the preamble of this proposed rule. As we discuss in the sections that follow, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking. Interested parties should continue to submit any comments and suggestions for FY 2023 by November 1, 2021 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*.

As we did for the FY 2021 IPPS/LTCH PPS proposed rule, for this FY 2022 IPPS/LTCH PPS proposed rule we are providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 39, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that this test software reflects the proposed GROUPER logic for FY 2022. Therefore, it includes the new diagnosis and procedure codes that are effective for FY 2022 as reflected in Table 6A.—New Diagnosis Codes—FY 2022 and Table 6B.—New Procedure Codes—FY 2022 associated with this proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2022 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2022 and Table 6D.—Invalid Procedure Codes—FY 2022 associated with this proposed rule. These tables are not published in the Addendum to this proposed rule, but are available via the

internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. Because the diagnosis and procedure codes no longer valid for FY 2022 are not reflected in the test software, we are making available a supplemental file in Table 6P.1a that includes the mapped Version 39 FY 2022 ICD–10–CM codes and the deleted Version 38 FY 2021 ICD–10–CM codes that should be used for testing purposes with users' available claims data. In addition, we are making available a supplemental file in Table 6P.1b that includes the mapped Version 39 FY 2022 ICD–10–PCS codes and the deleted Version 38 FY 2021 ICD–10–PCS codes that should be used for testing purposes with users' available claims data. Therefore, users will have access to the test software allowing them to build case examples that reflect the proposals included in this proposed rule. In addition, users will be able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 39.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 39, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 39, and the supplemental mapping files in Table 6P.1a and Table 6P.1b of the FY 2021 and FY 2022 ICD–10–CM diagnosis and ICD–10–PCS procedure codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Following are the changes that we are proposing to the MS–DRGs for FY 2022. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. As discussed in section I.F of the preamble of this proposed rule, we are proposing to use claims data from the March 2020 update of the FY 2019 MedPAR file in our analysis of proposed MS–DRG classification changes for FY 2022, consistent with our goal of using the best available data overall for ratesetting. Alternatively, we are also providing the results of our analysis of proposed MS–DRG classification changes using claims data from the September 2020 update of the FY 2020 MedPAR file. As a result, for this FY 2022 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the March 2020 update of the FY 2019 MedPAR file, which contains hospital bills received from October 1, 2018 through March 31, 2020, for discharges occurring through September 30, 2019. In addition, we also analyzed ICD–10 claims data from the September 2020 update of the FY 2020 MedPAR file, which contains hospital bills received from October 1, 2019 through September 30, 2020, for discharges occurring through September 30, 2020. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the ''March 2020 update of the FY 2019 MedPAR file'' and ''the September 2020 update of the FY 2020 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups. We also noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5—Proposed List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In our analysis of the MS–DRG classification requests for FY 2022 that we received by November 1, 2020, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for this FY 2022 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent two years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria is satisfied for a three way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two way split. If the criteria for both of the two way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three way split fails on any one of the five criteria and all five criteria for both two way splits (1_23 and 12_3) are met, we would apply the two way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two way splits, however we do not also evaluate the criteria for a three way split.

For this FY 2022 IPPS/LTCH PPS proposed rule, using the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, we also analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2022. Findings from our analysis indicated that approximately 32 MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we found that applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would result in the deletion of 96 MS–DRGs (32 MS–DRGs × 3 severity levels = 96) and the creation of 58 new MS–DRGs. These updates would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. We refer the reader to Table 6P.1c for the list of the 96 MS–DRGs that would be subject to deletion and the list of the 58 new MS–DRGs that would be proposed for creation for FY 2022 under this policy if the NonCC subgroup criteria were applied.

In light of the public health emergency (PHE), we have concerns about the impact of implementing this volume of MS–DRG changes at this time, and believe it may be appropriate to delay application of the NonCC subgroup criteria to existing MS–DRGs in order to maintain more stability in the current MS–DRG structure. Therefore, we are proposing to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2023, and proposing for FY 2022 to maintain the current structure of the 32 MS–DRGs that currently have a three-way severity level split (total of 96 MS–DRGs) that would otherwise be subject to these criteria.

2. Pre-MDC: MS–DRG 018 Chimeric Antigen Receptor (CAR) T-Cell Therapy

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we finalized our proposal to create Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) and to reassign cases reporting ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3) from Pre-MDC MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy), to new Pre-MDC MS–DRG 018 effective with discharges on and after October 1, 2020. We also finalized our proposal to revise the title for MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy'' to ''Autologous Bone Marrow Transplant with CC/MCC'' to reflect these changes.

Additionally, in the FY 2021 IPPS/LTCH PPS final rule in response to public comments expressing concern that Pre-MDC MS–DRG 018 is specific to one mechanistic approach to cellular therapy, and in response to commenters who sought clarification on how future CAR T-cell and non-CAR T-cell therapy products would be assigned, we stated that if additional cellular therapies should become available, we would use our established process to determine the MS–DRG assignment. The commenters requested that CMS provide flexibility for future cellular therapies, as they are made available and not restrict Pre-MDC MS–DRG 018 to CAR T-cell therapies alone. In this section of this rule, we discuss the assignment of these therapies in more detail.

During the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting, several topics involving requests for new procedure codes related to CAR T-cell therapies, non-CAR T-cell therapies and other immunotherapies were discussed. We refer the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding these requests for new procedure codes. As noted in prior rulemaking (85 FR 32543), for new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. As discussed in section II.D.13 of the preamble of this proposed rule, Table 6B.—New Procedure Codes, lists the new procedure codes that have been approved to date that will be effective with discharges on and after October 1, 2021. Included in Table 6B are the following new procedure codes that describe the administration of CAR T-cell and non-CAR T-cell therapies and other immunotherapies. Consistent with our established process, we examined the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment and, consistent with the assignment of those predecessor codes, we are proposing to classify the following new procedure codes as non-O.R. procedures affecting Pre-MDC MS–DRG 018, as shown in Table 6B.—New Procedure Codes associated with this proposed rule and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/*.

ICD-10-PCS Code	Description
XW033C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033H7	Introduction of axicabtagene ciloleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033J7	Introduction of tisagenlecleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033K7	Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033L7	Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033M7	Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW033N7	Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7
XW043C7	Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7
XW043G7	Introduction of allogeneic engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7
XW043H7	Introduction of axicabtagene ciloleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043J7	Introduction of tisagenlecleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043K7	Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043L7	Introduction of lifileucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043M7	Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7
XW043N7	Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7

In connection with our proposed assignment of the listed procedure codes to Pre-MDC MS–DRG 018, we are also proposing to revise the title for Pre-MDC MS–DRG 018 ''Chimeric Antigen Receptor (CAR) T-cell Immunotherapy'' to ''Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies'' to better reflect the cases reporting the administration of non-CAR T-cell therapies and other immunotherapies that would also be assigned to this MS–DRG (for example, Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7), in addition to CAR T-cell therapies.

3. MDC 03 (Diseases and Disorders of Ear, Nose and Throat)

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58462 through 58471), we finalized our proposal to create two new base MS–DRGs, 140 and 143, with a three-way severity level split for new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We provided the list of procedure codes that were finalized to define the logic for the new MS–DRGs in Tables 6P.2a, 6P.2b, and 6P.2c associated with the final rule and available via the internet on the CMS website at *https://www.cms.gov/*

Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/. We received two separate but related requests to review and reconsider the MS–DRG assignments for a subset of the procedure codes listed in Table 6P.2a (procedure codes assigned to MS–DRGs 140, 141, and 142) and Table 6P.2b (procedure codes assigned to MS–DRGs 143, 144, and 145). In this section of this proposed rule, we discuss each of these separate, but related requests.

a. Major Head and Neck Procedures

The requestor provided the following procedure codes from Table 6P.2a associated with the FY 2021 IPPS/LTCH PPS final rule for CMS to examine.

ICD-10-PCS Code	Description
0JB60ZZ	Excision of chest subcutaneous tissue and fascia, open approach
0JB70ZZ	Excision of back subcutaneous tissue and fascia, open approach
0JB80ZZ	Excision of abdomen subcutaneous tissue and fascia, open approach
0W9100Z	Drainage of cranial cavity with drainage device, open approach
0W910ZZ	Drainage of cranial cavity, open approach
0WC10ZZ	Extirpation of matter from cranial cavity, open approach
0WC13ZZ	Extirpation of matter from cranial cavity, percutaneous approach
0WC14ZZ	Extirpation of matter from cranial cavity, percutaneous endoscopic approach

The requestor stated that the listed procedure codes do not appear appropriately assigned to MS–DRGs 140, 141, and 142. According to the requestor, if any one of the five procedure codes describing a procedure performed on the cranial cavity (0W9100Z, 0W910ZZ, 0WC10ZZ, 0WC13ZZ, or 0WX14ZZ) is assigned in conjunction with a principal diagnosis from MDC 03 (Diseases and Disorders of Ear, Nose, Mouth, and Throat), it appears more appropriate that cases reporting the diagnosis and procedure combination would group to MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) (for example, ''craniotomy'' MS–DRGs) in MDC 01 (Diseases and Disorders of the Central Nervous System) or to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). The requestor stated that drainage and extirpation from the cranial cavity always involves drilling or cutting through the skull regardless of the approach, therefore the five procedure codes identified warrant assignment to the ''craniotomy'' MS–DRGs. For the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ), the requestor stated those codes should group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) because they are not pertinent to the ear, nose, mouth, or throat.

We reviewed this request and note that the five procedure codes describing procedures performed on the cranial cavity are already assigned to MDC 01 and group to the ''craniotomy'' MS–DRGs (25, 26, and 27) when reported with a principal diagnosis from MDC 01, and are also currently classified as Extensive O.R. procedures, resulting in assignment to MS–DRGs 981, 982, and 983 when any one of the five procedure codes is reported on the claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We also note that in addition to MS–DRGs 25, 26, and 27, MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) include procedures performed on structures located within the cranial cavity, are included in the range of MS–DRGs known as the ''craniotomy'' MS–DRGs in MDC 01, and the five procedure codes submitted by the requestor describing procedures performed on the cranial cavity are also assigned to these MS–DRGs. We refer the requestor to Appendix E of the ICD–10 MS–DRG Definitions Manual for further discussion of how each procedure code may be assigned to multiple MDCs and MS–DRGs under the IPPS. The ICD–10 MS–DRG Definitions Manual is located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*. We also note that these five procedure codes were previously assigned to MS–DRGs 131 and 132 (Cranial and Facial Procedures with and without CC/MCC, respectively) in MDC 03 under version 37 of the ICD–10 MS–DRGs prior to the restructuring that was finalized effective FY 2021 for MS–DRG 129 (Major Head and Neck Procedures with CC/MCC or Major Device) and MS–DRG 130 (Major Head and Neck Procedures without CC/MCC), MS–DRGs 131 and 132, and MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with and without CC/MCC, respectively).

With regard to the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ), the requestor suggested that the codes should group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) specifically because they are not pertinent to the ear, nose, mouth, or throat, however, it is unclear if the requestor was concerned more broadly that the three procedure codes should not group to any MS–DRGs in MDC 03 (Diseases and Disorders of Ear, Nose and Throat), given the stated rationale for the request.

Upon our review, we believe that the three procedure codes describing excision of subcutaneous tissue of chest, back, and abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ), which do not describe major head and neck procedures, were inadvertently included in Table 6P.2a for assignment to MS–DRGs 140, 141, and 142. However, we also believe that the codes are appropriate for assignment

in MDC 03 and note that the three procedure codes were previously assigned to MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with and without CC/MCC, respectively) in MDC 03 prior to the restructuring that was finalized effective FY 2021 for MS–DRGs 129, 130, 131, 132, 133, and 134. We also provided the following clarification in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58470), as stated in the ICD–10 MS–DRG Definitions Manual, ''In each MDC there is usually a medical and a surgical class referred to as ''other medical diseases'' and ''other surgical procedures,'' respectively. The ''other'' medical and surgical classes are not as precisely defined from a clinical perspective. The other classes would include diagnoses or procedures, which were infrequently encountered or not well defined clinically. For example, the ''other'' medical class for the Respiratory System MDC would contain the diagnoses ''other somatoform disorders'' and ''congenital malformation of the respiratory system,'' while the ''other'' surgical class for the female reproductive MDC would contain the surgical procedures ''excision of liver'' (liver biopsy in ICD–9–CM) and ''inspection of peritoneal cavity'' (exploratory laparotomy in ICD–9–CM). The ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC.''

During our review of procedure codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ (describing excision of subcutaneous tissue of chest, back, and abdomen, respectively) we also confirmed that these procedures are currently designated as Extensive O.R. procedures. Consistent with other procedure codes on the Non-extensive procedure code list, we do not believe the procedures described by these procedure codes necessarily utilize the resources or have the level of technical complexity as the procedures on the Extensive O.R. procedures list. Therefore, we agree that the procedure codes describing these procedures would be more appropriately designated as Non-extensive procedures and group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when any one of the three procedure codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We refer the reader to section II.D.10. of the preamble of this proposed rule for further discussion regarding our proposal to reassign these procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Therefore, we are proposing to reassign the three procedure codes describing excision of subcutaneous tissue of chest, back, or abdomen (0JB60ZZ, 0JB70ZZ, and 0JB80ZZ) from MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 03 for FY 2022. We refer the reader to section II.D.10. of the preamble of this proposed rule for further discussion regarding the designation of these codes as Extensive O.R. procedures versus Non-extensive O.R. procedures and our proposed reassignment of these codes from MS–DRGs 981, 982, and 983 to MS–DRGs 987, 988, and 989 for FY 2022.

b. Other Ear, Nose, Mouth and Throat O.R. Procedures

As stated earlier, we received two separate but related requests to review and reconsider the MS–DRG assignments for a subset of the procedure codes listed in Table 6P.2a and Table 6P.2b. In this section of this proposed rule, we discuss the second request related to procedure codes listed in Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule and currently assigned to MS–DRGs 143, 144 and 145.

The requestor provided a list of 82 procedure codes from Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule for CMS to examine. We refer the reader to Table 6P.1d associated with this FY 2022 IPPS/LTCH PPS proposed rule and available via the internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/* for the list of procedure codes that were provided by the requestor. According to the requestor, if any one of the 82 procedure codes is assigned in conjunction with a principal diagnosis code from MDC 03, it appears more appropriate that cases reporting the diagnosis and procedure code combination would group to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) versus MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). However, the requestor also stated that of the 82 procedure codes, the following three procedure codes describing control of bleeding in the cranial cavity warrant grouping to MS–DRGs 25, 26, and 27 (for example, ''craniotomy'' MS–DRGs) in MDC 01, for the same reasons previously described in the prior section pertaining to the five other procedures performed on the cranial cavity.

ICD-10-PCS Code	Description
0W310ZZ	Control bleeding in cranial cavity, open approach
0W313ZZ	Control bleeding in cranial cavity, percutaneous approach
0W314ZZ	Control bleeding in cranial cavity, percutaneous endoscopic approach

We reviewed this request and similar to the discussion in the prior section for the separate but related request, we note that the ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. We continue to believe that the 82

procedure codes provided by the requestor are appropriately assigned to MS–DRGs 143, 144, and 145 in MDC 03. With regard to the requestor's assertion that cases reporting any one of the 82 procedure codes would more appropriately group to the MS–DRGs for Extensive O.R. procedures or Non-extensive O.R. procedures when reported in conjunction with a principal diagnosis from MDC 03, we note that, as shown in Table 6P.2b associated with the FY 2021 IPPS/LTCH PPS final rule, the procedure codes that were finalized for assignment to MS–DRGs 143, 144, and 145 were previously assigned to MS–DRGs 129 and 130, 131 and 132, or 133 and 134 in MDC 03. We also note that, as discussed in prior rulemaking, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. For these reasons, we are proposing to maintain the current structure for MS–DRGs 143, 144, and 145 for FY 2022.

With regard to the three procedure codes describing control of bleeding in the cranial cavity (0W310ZZ, 0W313ZZ, and 0W314ZZ), and the requestor's suggestion that the codes should group to MS–DRGs 25, 26, and 27 in MDC 01, we consulted with our clinical advisors who stated these procedures are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 25, 26, and 27. We refer the reader to section II.D.10. of the preamble of this proposed rule for further discussion of this request, as well as our proposed assignment of these codes to MS–DRGs 23, 24, 25, 26, and 27 for FY 2022.

4. MDC 04 (Diseases and Disorders of the Respiratory System)

a. Bronchiectasis

We received a request to reassign cases reporting diagnosis codes describing bronchiectasis from MS–DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 177, 178, and 179 (Respiratory Infections and Inflammation with MCC, with CC, and without CC/MCC, respectively). Bronchiectasis is described by the following diagnosis codes

ICD-10-CM Code	Description
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
Q33.4	Congenital bronchiectasis

According to the requestor, the underlying pathophysiology of bronchiectasis is more similar to cystic fibrosis than it is to chronic obstructive pulmonary disease (COPD). The requestor stated that in bronchiectasis, there is an inciting event that creates scarring in the lung which prevents the lung from clearing out mucous like it normally would. The accumulation of abnormal mucous results in an environment conducive to bacterial growth and commonly found bacteria in this setting is very similar to those of cystic fibrosis with staphylococcus aureus, pseudomonas aeruginosa, and non-tuberculous mycobacterium. The requestor reported that when patients develop an exacerbation of bronchiectasis, this is because of a buildup of mucous compounded by overwhelming growth of the previously mentioned bacteria. The requestor also stated that patients admitted to the hospital for bronchiectasis exacerbation are treated aggressively with intravenous (IV) antibiotics to suppress the bacterial infection in combination with airway clearance therapies. The requestor further stated that, unlike in an acute COPD exacerbation, these patients do not always require steroids as there is not necessarily airway reactivity.

The requestor maintained that the underlying reason for admission to the hospital for these patients is the bacterial infection component of the exacerbation, with the standard course of treatment for these pulmonary bacterial infections averaging a minimum of 10–14 days due to the slow growing nature of the bacteria commonly encountered in these patients.

We reviewed this request and believe that bronchiectasis is appropriately assigned to MS–DRGs 190, 191, and 192 (Chronic Obstructive Pulmonary Disease with MCC, with CC, and without CC/MCC, respectively) because bronchiectasis, like COPD, is a chronic condition. With respect to the requestor's comments, cystic fibrosis, a genetic disease that affects mucous producing cells resulting in recurring lung infections, can lead to bronchiectasis. However, our clinical advisors indicated that the cause of bronchiectasis can be multifactorial or even remain undefined. Regardless of the cause, when present, bronchiectasis is an irreversible chronic pulmonary condition due to abnormal change to or destruction of normal pulmonary anatomy (the major bronchi and bronchiole walls), resulting in impaired air movement in and out of the lungs. COPD, regardless of the cause (smoking, pollution, other exposures), is a chronic pulmonary condition due to change/destruction of normal pulmonary anatomy, resulting in impaired air movement in and out of the lungs. Both bronchiectasis and COPD patients have abnormal pulmonary function tests and abnormal anatomic findings on chest x-ray and/or chest CT. Therefore, for these reasons, we are proposing to maintain the structure of MS–DRGs 190, 191, and 192 for FY 2022.

b. Major Chest Procedures

In the FY 2020 IPPS/LTCH PPS proposed (84 FR 19234) and final rules (84 FR 42148), we stated that in review of the procedures that are currently assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC and without CC/MCC, respectively) and 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively), that further refinement of these MS–DRGs may be warranted. In this section of this proposed rule, we discuss our review of the procedures and our proposal for

restructuring these MS–DRGs for FY 2022.

We began our review of MS–DRGs 163, 164, 165, 166, 167, and 168 by first examining all the procedures currently assigned to these MS–DRGs. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 38.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for complete documentation of the GROUPER logic for MS–DRGs 163, 164, 165, 166, 167, and 168.

In our review of the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168, we found 17 procedure codes in MS–DRGs 163, 164, and 165 describing laser interstitial thermal therapy (LITT) of body parts that do not describe areas within the respiratory system, which would not be clinically appropriate to maintain in the logic. These procedure codes are listed in the following table.

ICD-10-PCS Code	Description
D0Y6KZZ	Laser interstitial thermal therapy of spinal cord
D0Y7KZZ	Laser interstitial thermal therapy of peripheral nerve
DDY0KZZ	Laser interstitial thermal therapy of esophagus
DDY1KZZ	Laser interstitial thermal therapy of stomach
DDY2KZZ	Laser interstitial thermal therapy of duodenum
DDY3KZZ	Laser interstitial thermal therapy of jejunum
DDY4KZZ	Laser interstitial thermal therapy of ileum
DDY5KZZ	Laser interstitial thermal therapy of colon
DDY7KZZ	Laser interstitial thermal therapy of rectum
DDY8KZZ	Laser interstitial thermal therapy of anus
DFY1KZZ	Laser interstitial thermal therapy of gallbladder
DFY2KZZ	Laser interstitial thermal therapy of bile ducts
DFY3KZZ	Laser interstitial thermal therapy of pancreas
DGY2KZZ	Laser interstitial thermal therapy of adrenal glands
DMY0KZZ	Laser interstitial thermal therapy of left breast
DMY1KZZ	Laser interstitial thermal therapy of right breast
DVY0KZZ	Laser interstitial thermal therapy of prostate

During our review of these 17 procedure codes, we identified additional MDCs and MS–DRG assignments that are also not clinically appropriate to maintain in the logic because the body parts described by the codes are not consistent with the organ system, etiology or clinical specialty of the MDC to which the procedure code is currently assigned. For example, 16 of the 17 procedure codes (all except procedure code DVY0KZZ) are included in the logic for case assignment to MDC 12 (Diseases and Disorders of the Male Reproductive System) in MS–DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with and without CC/MCC, respectively) and MS–DRGs 717 and 718 (Other Male Reproductive System O.R. Procedures Except Malignancy with and without CC/MCC, respectively) which is not clinically appropriate. Therefore, we are proposing to reassign these 17 procedure codes from their current MS–DRG assignments in MDC 04, and from the additional MDCs and MS–DRGs identified during our review that were found to be clinically inappropriate, to their clinically appropriate MDC and MS–DRGs as shown in Table 6P.2b associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

During our review of the procedure codes describing LITT of various body parts we also confirmed that these procedures are currently designated as Extensive O.R. procedures. We do not believe the procedures described by these procedure codes necessarily utilize the resources or have the level of technical complexity as the other procedures on the Extensive O.R. procedures list. We believe that the procedure codes describing these procedures would be more appropriately designated as Non-extensive procedures and group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when any one of the procedure codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We refer the reader to section II.D.10. of the preamble of this proposed rule for further discussion regarding our proposal to reassign these procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

We also identified five procedure codes describing repair of the esophagus procedures currently assigned to MS–DRGs 163, 164, and 165 that would not be clinically appropriate to maintain in the logic. The procedure codes are 0DQ50ZZ (Repair esophagus, open approach), 0DQ53ZZ (Repair esophagus, percutaneous approach), 0DQ54ZZ (Repair esophagus, percutaneous

endoscopic approach), 0DQ57ZZ (Repair esophagus, via natural or artificial opening), and 0DQ58ZZ (Repair esophagus, via natural or artificial opening endoscopic), and are currently assigned to the following MDCs and MS–DRGs.

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MDC	Description	MS-DRG	Description
03	Diseases and Disorders of the Ear, Nose, Mouth and Throat	143	Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC
		144	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC
		145	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC
06	Diseases and Disorders of the Digestive System	326	Stomach, Esophageal and Duodenal Procedures with MCC
		327	Stomach, Esophageal and Duodenal Procedures with CC
		328	Stomach, Esophageal and Duodenal Procedures without CC/MCC
17	Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms	820	Lymphoma and Leukemia with Major O.R. Procedures with MCC
		821	Lymphoma and Leukemia with Major O.R. Procedures with CC
		822	Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC
		826	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC
		827	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with CC
		828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures without CC/MCC

21	Injuries, Poisonings and Toxic Effects of Drugs	907	Other O.R. Procedures for Injuries with MCC
		908	Other O.R. Procedures for Injuries with CC
		909	Other O.R. Procedures for Injuries without CC/MCC
24	Multiple Significant Trauma	957	Other O.R. Procedures for Multiple Significant Trauma with MCC
		958	Other O.R. Procedures for Multiple Significant Trauma with CC
		959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC

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The five procedure codes describing repair of esophagus procedures are not clinically coherent with the other procedures in MS–DRGs 163, 164, and 165 that describe procedures performed on major chest structures. Therefore, we are proposing to remove procedure codes 0DQ50ZZ, 0DQ53ZZ, 0DQ54ZZ, 0DQ57ZZ, and 0DQ58ZZ from the logic in MDC 04 for FY 2022.

During our review of procedure codes 0DQ50ZZ, 0DQ53ZZ, 0DQ54ZZ, 0DQ57ZZ, and 0DQ58ZZ (describing repair of esophagus procedures) we also confirmed that these procedures are currently designated as Extensive O.R. procedures. We do not believe the procedures described by procedure codes 0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ necessarily utilize the resources or have the level of technical complexity as the other procedures on the Extensive O.R. procedures list. We believe that the procedure codes describing these procedures would be more appropriately designated as Non-extensive procedures and group to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when any one of the three procedure codes is reported on a claim and is unrelated to the MDC to which the case was assigned based on the principal diagnosis. We refer the reader to section II.D.10. of the preamble of this proposed rule for further discussion regarding our proposal to reassign these procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

Next, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 163, 164, 165, 166, 167, and 168. Our findings are shown in the following tables.

March 2020 Update of the FY 2019 MedPAR File			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
163	10,851	11.7	$34,904
164	15,743	5.4	$19,258
165	8,144	3.1	$14,120
166	10,151	10.6	$26,677
167	6,483	5.0	$13,517
168	2,420	2.6	$10,117

September 2020 Update of the FY 2020 MedPAR File			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
163	9,227	11.1	$35,694
164	13,121	5.1	$19,786
165	6,339	3.0	$14,991
166	8,213	10.7	$27,939
167	4,889	5.0	$14,288
168	1,726	2.5	$10,566

As shown in the tables, there were a higher number of cases reported in MS–DRGs 163, 164, 165, 166, 167, and 168 from the March 2020 update of the FY 2019 MedPAR file in comparison to the September 2020 update of the FY 2020 MedPAR file and overall, the cases reported have comparable average lengths of stay and comparable average costs for both fiscal years.

We then examined claims data from both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 163, 164, 165, 166, 167, and 168 to compare costs, complexity of service and clinical coherence for each procedure code currently assigned to these MS–DRGs to assess any potential reassignment of the procedures. We refer the reader to Table 6P.1e and Table 6P.1f associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the detailed claims data analysis. Table 6P.1e contains the data analysis findings of procedure codes currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 from the March 2020 update of the FY 2019 MedPAR file and Table 6P.1f contains the data analysis findings of procedure codes currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 from the September 2020 update of the FY 2020 MedPAR file. We note that if a procedure code that is currently assigned to MS–DRGs 163, 164, 165, 166, 167, or 168 is not displayed, it is because there were no cases found reporting that code in the assigned MS–DRG.

As shown in Table 6P.1e and Table 6P.1f associated with this proposed rule, in our examination of the claims data from both the March 2020 update of the FY 2019 MedPAR file and September 2020 update of the FY 2020 MedPAR file, we found there is wide variation in the volume, length of stay, and average costs for the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168. There were several instances in which only one occurrence of a procedure was reported with a procedure code from MS–DRGs 163, 164, 165, 166, 167, or 168, and the average length of stay for these specific cases ranged from 1 day to 97 days. For example, in the analysis of claims data from the March 2020 update of the FY 2019 MedPAR file, during our review of MS–DRG 163, we found 153 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 2 days to 65 days and the average costs ranging from $3,760 to $195,447 for these cases. For MS–DRG 164, we found 145 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 28 days and the average costs ranging from $1,886 to $137,810 for these cases. For MS–DRG 165, we found 111 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 23 days and the average costs ranging from $2,656 to $73,092 for these cases. For MS–DRG 166, we found 150 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 61 days and the average costs ranging from $3,230 to $246,679 for these cases. For MS–DRG 167, we found 110 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 23 days and the average costs ranging from $2,058 to $149,220 for these cases. For MS–DRG 168, we found 68 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 18 days and the average costs ranging from $2,033 to $35,576 for these cases.

Our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file resulted in similar findings to those from the March 2020 update of the FY 2019 MedPAR file; there were several instances in which only one occurrence of a procedure was reported with a procedure code from MS–DRGs 163, 164, 165, 166, 167, or 168. During our review of MS–DRG 163, we found 139 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 2 days to 97 days and the average costs ranging from $5,697 to $205,696 for these cases. For MS–DRG 164, we found 122 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 35 days and the average costs ranging from $3,204 to $120,128 for these cases. For MS–DRG 165, we found 92 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 16 days and the average costs ranging from $2,682 to $164,014 for these cases. For MS–DRG 166, we found 141 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 45 days and the average costs ranging from $3,230 to $246,679 for these cases. For MS–DRG 167, we found 105 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 22 days and the average costs ranging from $2,150 to $112,465 for these cases. For MS–DRG 168, we found 72 procedures for which only one occurrence of the procedure was reported with the average length of stay ranging from 1 day to 9 days and the average costs ranging from $1,563 to $76,061 for these cases.

Our clinical advisors reviewed the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 to identify the patient attributes that currently define each of these procedures and to group them with respect to complexity of service and resource intensity. This process included separating the procedures according to the surgical approach (open, percutaneous, percutaneous endoscopic, via natural or artificial opening, via natural or artificial opening endoscopic, and external).

We also considered the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 163, 164, 165, 166, 167, and 168 to further analyze the average length of stay and average costs for the cases reporting procedures assigned to any one of these MS–DRGs as well as clinical coherence for these cases. For example, procedures that we believe represent greater treatment difficulty and reflect a class of patients who are similar clinically with regard to consumption of hospital resources were grouped separately from procedures that we believe to be less complex but still reflect patients who are similar clinically with regard to consumption of hospital resources. This approach differentiated the more complex procedures, such as procedures performed on the sternum and ribs (for example, major chest) from the less complex procedures such as bypass procedures performed on peripheral vessels or diagnostic biopsies.

As an initial step in our proposed restructuring of these MS–DRGs, we identified the following 26 procedure codes that are currently assigned to MS–DRGs 166, 167, and 168 that we believe represent procedures performed on structures that align more appropriately with the procedures assigned to MS–DRGs 163, 164, and 165 that describe major chest procedures.

ICD-10-PCS Code	Description
02QP4ZZ	Repair pulmonary trunk, percutaneous endoscopic approach
02QQ0ZZ	Repair right pulmonary artery, open approach
02QQ4ZZ	Repair right pulmonary artery, percutaneous endoscopic approach
02QR0ZZ	Repair left pulmonary artery, open approach
02QR4ZZ	Repair left pulmonary artery, percutaneous endoscopic approach
02QW0ZZ	Repair thoracic aorta, descending, open approach
02QW4ZZ	Repair thoracic aorta, descending, percutaneous endoscopic approach
02QX0ZZ	Repair thoracic aorta, ascending/arch, open approach
02QX4ZZ	Repair thoracic aorta, ascending/arch, percutaneous endoscopic approach
0PH000Z	Insertion of rigid plate internal fixation device into sternum, open approach
0PH004Z	Insertion of internal fixation device into sternum, open approach
0PH040Z	Insertion of rigid plate internal fixation device into sternum, percutaneous endoscopic approach
0PH044Z	Insertion of internal fixation device into sternum, percutaneous endoscopic approach
0PH144Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous endoscopic approach
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach
0PH244Z	Insertion of internal fixation device into 3 or more ribs, percutaneous endoscopic approach
0PQ00ZZ	Repair sternum, open approach
0PQ04ZZ	Repair sternum, percutaneous endoscopic approach
0PS10ZZ	Reposition 1 to 2 ribs, open approach
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach
0PS20ZZ	Reposition 3 or more ribs, open approach
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach
0PT00ZZ	Resection of sternum, open approach
0PT10ZZ	Resection of 1 to 2 ribs, open approach
0PT20ZZ	Resection of 3 or more ribs, open approach

We analyzed claims data from the March 2020 update of the FY 2019 MedPAR file for the listed procedure codes in MS–DRGs 166, 167, and 168. We note that if a listed procedure code is not displayed, it is because there were no cases found reporting that code among MS–DRGs 166, 167, and 168. Our findings are shown in the following table.

ICD-10-PCS Code	Description	Frequency	Average Length of Stay	Average Costs
02QR0ZZ	Repair left pulmonary artery, open approach	1	1	$3,463
02QW0ZZ	Repair thoracic aorta, descending, open approach	1	15	$46,829
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach	5	6.4	$23,032
0PQ00ZZ	Repair sternum, open approach	1	11	$18,388
0PS10ZZ	Reposition 1 to 2 ribs, open approach	2	6.0	$22,019
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach	2	8.5	$25,123
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach	288	9.47	$44,510
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach	3	5.67	$37,069
0PT10ZZ	Resection of 1 to 2 ribs, open approach	9	10.58	$22,901
0PT20ZZ	Resection of 3 or more ribs, open approach	2	73.5	$183,630

We then analyzed claims data from the September 2020 update of the FY 2020 MedPAR file for the listed procedure codes in MS–DRGs 166, 167, and 168. We note that if a listed procedure code is not displayed, it is because there were no cases found reporting that code among MS–DRGs 166, 167, and 168. Our findings are shown in the following table.

ICD-10-PCS Code	Description	Frequency	Average Length of Stay	Average Costs
02QX0ZZ	Repair thoracic aorta, ascending/arch, open approach	2	20	$134,670
0PH000Z	Insertion of rigid plate internal fixation device into sternum, open approach	2	11.5	$58,192
0PH004Z	Insertion of internal fixation device into sternum, open approach	4	18.5	$34,164
0PH044Z	Insertion of internal fixation device into sternum, percutaneous endoscopic approach	1	6	$19,501
0PH144Z	Insertion of internal fixation device into 1 to 2 ribs, percutaneous endoscopic approach	3	7.7	$26,846
0PH204Z	Insertion of internal fixation device into 3 or more ribs, open approach	18	10.1	$39,546

0PH244Z	Insertion of internal fixation device into 3 or more ribs, percutaneous endoscopic approach	1	10	$40,069
0PQ00ZZ	Repair sternum, open approach	5	6.4	$31,049
0PS10ZZ	Reposition 1 to 2 ribs, open approach	1	16	$147,493
0PS144Z	Reposition 1 to 2 ribs with internal fixation device, percutaneous endoscopic approach	3	8.3	$25,944
0PS204Z	Reposition 3 or more ribs with internal fixation device, open approach	344	9.6	$48,340
0PS20ZZ	Reposition 3 or more ribs, open approach	1	12	$22,535
0PS244Z	Reposition 3 or more ribs with internal fixation device, percutaneous endoscopic approach	5	5.2	$38,618
0PT00ZZ	Resection of sternum, open approach	1	3.0	$7,072
0PT10ZZ	Resection of 1 to 2 ribs, open approach	7	7.9	$29,222
0PT20ZZ	Resection of 3 or more ribs, open approach	3	13	$32,933

We refer the reader to Tables 6P.1e and 6P.1f for detailed claims data for the previously listed procedures in MS–DRGs 163, 164, 165, 166, 167, and 168 from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, respectively, and note that while some of the 26 listed procedure codes identified in MS–DRGs 166, 167, and 168 may not have been reported in either year's MedPAR claims data or only had one occurrence in which the procedure was reported, we believe these procedures described by the listed 26 procedure codes are clinically coherent with the other procedures that are currently assigned to MS–DRGs 163, 164, and 165. For example, in our analysis of the March 2020 update of the FY 2019 MedPAR file, as shown in the table, we found procedure code 02QW0ZZ reported with one occurrence with an average length of stay of 15 days and average costs of $46,829. Despite finding only one case, we believe procedures described by this procedure code, as well as related procedure codes describing procedures performed on the great vessels, are more clinically coherent with the procedures assigned to MS–DRGs 163, 164, and 165 and align more appropriately with the average length of stay and average costs of those MS–DRGs. Similarly, in our analysis of the September 2020 update of the FY 2020 MedPAR file, as shown in the table, we found procedure code 0PS204Z reported with 344 occurrences with an average length of stay of 9.6 days and average costs of $48,340. We believe procedures described by this procedure code, as well as related procedure codes describing procedures performed to repair or resect the ribs, are more clinically coherent with the procedures assigned to MS–DRGs 163, 164, and 165 and also align more appropriately with the average length of stay and average costs of those MS–DRGs.

As a result of our preliminary review of MS–DRGs 163, 164, 165, 166, 167, and 168, for FY 2022 we are proposing the reassignment of the listed 26 procedure codes (9 procedure codes describing repair of pulmonary or thoracic structures, and 17 procedure codes describing procedures performed on the sternum or ribs) from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165 in MDC 04. Our data analysis shows that for the cases reporting any one of the 26 procedure codes, generally, they have an average length of stay and average costs that appear more consistent with the average length of stay and average costs of cases in MS–DRGs 163, 164, and 165. Our clinical advisors also agree that these procedures clinically align with the other procedures that are currently assigned to MS–DRGs 163, 164, and 165. We refer the reader to Table 6P.2c associated with this proposed rule for the list of procedure codes we are proposing for reassignment from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165 in MDC 04.

After this initial review of all the procedures currently assigned to MS–DRGs 163, 164, 165, 166, 167, and 168, in combination with the results of the data analysis as reflected in Tables 6P.1e and 6P.1f, our clinical advisors support a phased restructuring of these MS–DRGs. We believe further analysis of the procedures assigned to these MS–DRGs is warranted based on the creation of new procedure codes that have been assigned to these MS–DRGs in recent years for which claims data are not yet available and the need for additional time to examine the procedures currently assigned to those MS–DRGs by clinical intensity, complexity of service and resource utilization. We will continue to evaluate the procedures assigned to these MS–DRGs as additional claims data become available.

5. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Short-Term External Heart Assist Device

Impella® Ventricular Support Systems are temporary heart assist devices intended to support blood pressure and provide increased blood flow to critical organs in patients with cardiogenic shock, by drawing blood out of the heart and pumping it into the aorta, partially or fully bypassing the left ventricle to provide adequate circulation of blood (replace or supplement left ventricle pumping) while also allowing damaged heart muscle the opportunity to rest and recover in patients who need short-term support for up to 6 days. The ICD–10–PCS codes that describe the insertion of Impella® heart assist devices are

currently assigned to MS–DRG 215 (Other Heart Assist System Implant). We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 38.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRG 215.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41159 through 41170), we discussed public comments that recommended that CMS continue to monitor the data in MS–DRG 215 for future consideration of distinctions (for example, different approaches and evolving technologies) that may impact the clinical and resource use of procedures utilizing heart assist devices. Our data analysis showed a wide range in the average length of stay and the average costs for cases reporting procedures that involve a biventricular short-term external heart assist system versus a short-term external heart assist system. We noted we were aware that the AHA published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices due to the technology being approved for new indications but the claims data current at that time did not yet reflect that updated guidance. We also noted that there had been recent updates to the descriptions of the codes for heart assist devices. The qualifier ''intraoperative'' was added effective October 1, 2017 (FY 2018) to the procedure codes describing the insertion of short-term external heart assist system procedures to distinguish between procedures where the device was only used intraoperatively and was removed at the conclusion of the procedure versus procedures where the device was not removed at the conclusion of the procedure and for which that qualifier would not be reported. We agreed with the commenters that continued monitoring of the data and further analysis was necessary prior to proposing any modifications to MS–DRG 215 and finalized our proposal to maintain the current structure of MS–DRG 215 for FY 2019.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42167) we discussed public comments on our proposals related to recalibration of the FY 2020 relative weights and the changes in relative weights from FY 2019. Several commenters expressed concern about significant reductions to the relative weight for MS–DRG 215. Commenters stated that the reduction in the proposed relative weight was 29 percent, the largest decrease of any MS–DRG; commenters also noted that the cumulative decrease to the relative weight for MS–DRG 215 would be 43 percent since FY 2017. Commenters stated that the proposed relative weights would result in significant underpayments to facilities, which would in turn limit access to heart assist devices. After reviewing the comments received and the data used in our ratesetting calculations, we acknowledged an outlier circumstance where the weight for a MS–DRG was seeing a significant reduction for each of the 3 years since CMS began using the ICD–10 data in calculating the relative weights. Therefore, for the reasons discussed in the FY 2020 final rule, we adopted a temporary one-time measure for FY 2020 where the FY 2020 relative weight was set equal to the FY 2019 relative weight, which in turn had been set equal to the FY 2018 relative weight.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58598) we again acknowledged an outlier circumstance where the weight for MS–DRG 215 was seeing a significant reduction for each of the 4 years since CMS began using the ICD–10 data in calculating the relative weights. We stated while we would ordinarily consider this weight change to be appropriately driven by the underlying data, given the comments received, and in an abundance of caution because this may be the MS–DRG assigned when a hospital provides temporary right ventricular support for up to 14 days in critical care patients for the treatment of acute right heart failure or decompensation caused by complications related to COVID–19, including pulmonary embolism, we adopted a temporary one-time measure for FY 2021 for MS–DRG 215. Specifically, we set the 2021 relative weight for MS–DRG 215 equal to the average of the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

For this FY 2022 IPPS/LTCH PPS proposed rule, we received a request to reassign certain cases reporting procedure codes describing the insertion of a percutaneous short-term external heart assist device from MS–DRG 215 to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). According to the requestor, there are two distinct clinical populations within MS–DRG 215: High-risk Percutaneous Coronary Intervention (PCI) patients receiving short term ''intraoperative'' external heart assist systems where the device is only used intraoperatively and is removed at the conclusion of the procedure, and those patients in or at risk of cardiogenic shock requiring longer heart pump support and ICU stays. The requestor stated that cases in which short-term external heart assist systems are placed intraoperatively require fewer resources. The requestor suggested that moving the less resource intensive cases that report a procedure code that describes the intraoperative insertion of short-term external heart assist systems from MS–DRG 215 into MS–DRG 216, 217, and 218, will clinically align the two distinctly different patient populations, and consequently will address the potential decrease in the relative weight of MS–DRG 215.

The requestor stated it performed its own analysis of claims in MS–DRG 215 that involve the intraoperative insertion of a short-term external heart assist device (as identified by the presence of ICD–10–PCS codes 02HA3RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous approach) and 5A0221D (Assistance with cardiac output using impeller pump, continuous). The requestor stated that its analysis found that if procedures involving intraoperative placement of a short-term external heart assist device were moved into MS–DRGs 216, 217 and 218, it would result in an increase in the average costs and average lengths of stay for the cases that would remain to be assigned to MS–DRG 215.

During our review of this issue, we noted that when a patient is admitted and has an Impella® external heart assist device inserted two ICD–10–PCS codes are assigned: A code that describes the insertion of the device and code 5A0221D that describes assistance with an impeller pump. Therefore, our analysis included procedure code 02HA3RJ as identified by the requestor as well as similar procedure codes 02HA0RJ (Insertion of short-term external heart assist system into heart, intraoperative, open approach) and 02HA4RJ (Insertion of short-term external heart assist system into heart, intraoperative, percutaneous endoscopic approach) that also describe the intraoperative insertion of a short-term heart assist device, differing only in approach. Because the assistance with an Impella® is coded with ICD–10–PCS code 5A0221D whether the device is used only intraoperatively or in instances where the device is left in place at the conclusion of the procedure, we did not include this code in our analysis. We also note that the requestor suggested that the cases reporting a procedure code describing

the intraoperative insertion of a short-term external heart assist device be moved to MS–DRGs 216, 217 and 218 but these MS–DRGs are defined by the performance of cardiac catheterization. Therefore, we expanded our analysis to also include MS–DRGs 219, 220 and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively).

First, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ and a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	7,741	7.8	$68,234
	All intraoperative short-term external heart assist devices with cardiac catheterization	2,943	7.1	$60,449
	02HA0RJ with cardiac catheterization	23	8.9	$85,806
	02HA3RJ with cardiac catheterization	2,904	7.1	$60,227
	02HA4RJ with cardiac catheterization	16	6.4	$64,217

As shown in the table, we identified a total of 7,741 cases within MS–DRG 215 with an average length of stay of 7.8 days and average costs of $68,234. Of these 7,741 cases, there are 2,943 cases that include both a procedure code describing the intraoperative insertion of a short-term external heart assist device and a procedure code describing the performance of a cardiac catheterization with an average length of stay of 7.1 days and average costs of $60,449. Of these 2,943 cases, there are 23 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.9 days and average costs of $85,806. There are 2,904 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 7.1 days and average costs of $60,227. There are 16 cases reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization approach with an average length of stay of 6.4 days and average costs of $64,217. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization, generally, the average length of stay is shorter and the average costs are lower than the average length of stay and average costs (with the exception of the average costs and length of stay for the 23 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization which are higher) compared to all cases in that MS–DRG.

We also examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRGs 216, 217 and 218. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
216	5,603	16.7	$74,413
217	1,885	9.5	$47,159
218	210	6.6	$37,778

Because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 216, 217, and 218, we also analyzed the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with MCC	1,886	9	$66,524
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with CC	778	4.1	$49,481
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization without CC/MCC	278	2.5	$49,942

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2019 MedPAR file for MS–DRGs 216, 217 and 218 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs of MS–DRGs 217 and 218, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215. The average costs of the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with MCC'' are lower than the average costs of both MS–DRGs 215 and 216.

Next, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	7,741	7.8	$68,234
	All intraoperative short-term external heart assist devices without cardiac catheterization	432	4.8	$53,607
	02HA0RJ without cardiac catheterization	8	8.8	$141,242
	02HA3RJ without cardiac catheterization	423	4.7	$51,964
	02HA4RJ without cardiac catheterization	1	2	$47,289

As shown in the table, of the 7,741 cases within MS–DRG 215, there are 432 cases that include a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.8 days and average costs of $53,607. Of these 432 cases, there are eight cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.8 days and average costs of $141,242. There are 423 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.7 days and average costs of $51,964. There is one case reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization approach with a length of stay of 2 days and costs of $47,289. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a

procedure code describing the performance of a cardiac catheterization, generally, the average length of stay is shorter and the average costs are lower than the average length of stay and average costs (with the exception of the average costs and length of stay for the eight cases describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization which are higher) compared to all cases in that MS–DRG.

We also examined claims data from the March 2020 update of the FY 2019 MedPAR file for MS–DRGs 219, 220 and 221. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	15,597	10.9	$57,845
220	15,074	6.5	$39,565
221	2,417	4.5	$33,560

Similarly, because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 219, 220 and 221, we also analyzed the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with MCC	205	7.3	$60,274
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with CC	158	2.7	$46,745
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization without CC/MCC	68	1.4	$41,050

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2019 MedPAR file for MS–DRGs 219, 220 and 221 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device, without a procedure code describing the performance of a cardiac catheterization ''with MCC'', ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs MS–DRGs 219, 220 and 221, respectively, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	6,275	7.9	$72,144
	All intraoperative short-term external heart assist devices with cardiac catheterization	2,395	6.8	$62,260
	02HA0RJ with cardiac catheterization	25	8.2	$85,954
	02HA3RJ with cardiac catheterization	2,360	6.8	$61,965
	02HA4RJ with cardiac catheterization	10	6.9	$72,564

As shown in the table, we identified a total of 6,275 cases within MS–DRG 215 with an average length of stay of 7.9 days and average costs of $72,144. Of these 6,275 cases, there are 2,395 cases that include both a procedure code describing the intraoperative insertion of a short-term external heart assist device and a procedure code describing the performance of a cardiac catheterization with an average length of stay of 6.8 days and average costs of $62,260. Of these 2,395 cases, there were 25 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.2 days and average costs of $85,954. There are 2,360 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization with an average length of stay of 6.8 days and average costs of $61,965. There are 10 cases reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization approach with an average length of stay of 6.9 days and average costs of $72,564. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization, when examined collectively, the average length of stay is shorter (6.8 days versus 7.9 days) and the average costs are lower ($62,260 versus $72,144) than the average length of stay and average costs (of all cases in that MS–DRG). There were some differences noted in cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization when examined by operative approach. For the 25 cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization, the average costs were higher ($85,954 versus $72,144) and average length of stay was slightly longer (8.2 days versus 7.9 days) when compared to all cases in that MS–DRG. For the 10 cases reporting a procedure code describing the percutaneous endoscopic intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization, the average costs were nearly equal ($72,564 versus $72,144) and average length of stay was shorter (6.9 days versus 7.9 days) when compared to all cases in that MS–DRG.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 216, 217 and 218. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
216	4,279	16.5	$79,786
217	1,310	9.4	$49,109
218	121	6.6	$43,504

Because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 216, 217, and 218, we also analyzed the cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with MCC	1,522	8.7	$68,543
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization with CC	632	3.8	$51,908
	02HA0RJ, 02HA3RJ or 02HA4RJ with cardiac catheterization without CC/MCC	241	2.5	$49,726

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ with a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2020 MedPAR file for MS–DRGs 216, 217 and 218 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs of MS–DRGs 217 and 218, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215. The average costs of the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device with a procedure code describing the performance of a cardiac catheterization ''with MCC'' are lower than the average costs of both MS–DRGs 215 and 216.

Next, we examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	6,275	7.9	$72,144
	All intraoperative short-term external heart assist devices without cardiac catheterization	331	4.5	$52,181
	02HA0RJ without cardiac catheterization	8	8.9	$80,314
	02HA3RJ without cardiac catheterization	322	4.4	$51,569
	02HA4RJ without cardiac catheterization	1	2	$24,379

As shown in the table, of the 6,275 cases within MS–DRG 215, there are 331 cases that include a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.5 days and average costs of $52,181. Of these 331 cases, there are eight cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 8.9 days and average costs of $80,314. There are 332 cases reporting a procedure code describing a percutaneous intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization with an average length of stay of 4.4 days and average costs of $51,569. There is one case reporting a procedure code describing a percutaneous endoscopic intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization approach with a length of stay of 2 days and costs of $24,379. The data analysis shows that for the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a

procedure code describing the performance of a cardiac catheterization, generally, the average length of stay is shorter and the average costs are lower than the average length of stay and average costs (with the exception of the average costs and length of stay for the eight cases reporting a procedure code describing the open intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization which are higher) compared to all cases in that MS–DRG.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for MS–DRGs 219, 220 and 221. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	11,863	10.9	$61,934
220	10,072	6.5	$41,800
221	1,440	4.2	$36,242

Similarly, because MS–DRG 215 is a base DRG and there is a three-way split within MS–DRGs 219, 220 and 221, we also analyzed the 331 cases reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with MCC	161	6.5	$57,285
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization with CC	103	3	$47,996
	02HA0RJ, 02HA3RJ or 02HA4RJ without cardiac catheterization without CC/MCC	67	1.7	$46,352

This data analysis shows the cases in MS–DRG 215 reporting ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ without a procedure code describing the performance of a cardiac catheterization when distributed based on the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC) have average costs generally more similar to the average costs in the FY 2020 MedPAR file for MS–DRGs 219, 220 and 221 respectively, while the average lengths of stay are shorter. While the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization ''with CC'' and ''without CC/MCC'' have higher average costs than the average costs of MS–DRGs 220 and 221, these costs are closer to the average costs of those MS–DRGs than they are to the average costs of MS–DRG 215. The average costs of the cases from MS–DRG 215 reporting a procedure code describing the intraoperative insertion of a short-term external heart assist device without a procedure code describing the performance of a cardiac catheterization ''with MCC'' are lower than the average costs of both MS–DRGs 215 and 219.

Our clinical advisors reviewed the clinical issues and the claims data and agreed that cases reporting a procedure code that describes the intraoperative insertion of a short-term external heart assist device are generally less resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of other types of heart assist devices currently assigned to MS–DRG 215. Our clinical advisors state that critically ill patients who are experiencing or at risk for cardiogenic shock from an emergent event such as heart attack or virus that impacts the functioning of the heart and requires longer heart pump support are different from those patients who require intraoperative support only. Patients receiving a short-term external heart assist device intraoperatively during coronary interventions often have an underlying disease pathology such as heart failure related to occluded coronary vessels that is broadly similar in kind to other patients also receiving these interventions without the need for an insertion of a short-term external heart assist device. In the post-operative period, these patients can recover and can be sufficiently rehabilitated prior to discharge. For these reasons, our clinical advisors support reassigning

ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device to MS–DRGs 216, 217, 218, 219, 220 and 221 in MDC 05. They stated this reassignment would improve clinical coherence in these MS–DRGs.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the Version 38.1 ICD–10 MS–DRG GROUPER and the claims data from the March 2020 update of the FY 2019 MedPAR file. The following table reflects our simulation for ICD–10–PCS procedure codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if they were moved to MS–DRGS 216, 217, 218, 219, 220 and 221.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
215	All Cases	7,741	7.8	$68,234
	without 02HA0RJ, 02HA3RJ or 02HA4RJ	4,798	8.2	$73,009
216	All Cases	5,603	16.7	$74,413
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	7,490	14.8	$72,424
217	All Cases	1,885	9.5	$47,159
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	2,663	7.9	$47,837
218	All Cases	210	6.6	$37,778
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	488	4.3	$44,708
219	All Cases	15,597	10.9	$57,845
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	17,484	10.7	$58,781
220	All Cases	15,074	6.5	$39,565
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	15,852	6.4	$40,052
221	All Cases	2,417	4.5	$33,560
	with 02HA0RJ, 02HA3RJ or 02HA4RJ	2,695	4.3	$35,250

We believe the resulting proposed MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use while at the same time addressing concerns related to the relative weight of MS–DRG 215. A review of this simulation shows that this distribution of ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if moved to MS–DRGs 216, 217, 218, 219, 220 and 221, increases the average costs of the cases remaining in MS–DRG 215 by over $4,500, while generally having a more limited effect on the average costs of MS–DRGs 216, 217, 218, 219, 220 and 221.

We also ran a simulation using the Version 38.1 ICD–10 MS–DRG GROUPER and the claims data from the September 2020 update of the FY 2020 MedPAR file. The following table reflects our simulation for ICD–10–PCS procedure codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if they were moved to MS–DRGS 216, 217, 218, 219, 220 and 221.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
	All Cases	6,275	7.9	$72,144
215	without 02HA0RJ, 02HA3RJ or 02HA4RJ	3,880	8.6	$78,245
	All Cases	4,279	16.5	$79,786
216	with 02HA0RJ, 02HA3RJ or 02HA4RJ	5,801	14.5	$76,835
	All Cases	1,310	9.4	$49,109
217	with 02HA0RJ, 02HA3RJ or 02HA4RJ	1,942	7.6	$50,020
	All Cases	121	6.6	$43,504
218	with 02HA0RJ, 02HA3RJ or 02HA4RJ	362	3.8	$47,646
	All Cases	11,863	10.9	$61,934
219	with 02HA0RJ, 02HA3RJ or 02HA4RJ	13,385	10.7	$62,685
	All Cases	10,072	6.5	$41,800
220	with 02HA0RJ, 02HA3RJ or 02HA4RJ	10,704	6.3	$42,397
	All Cases	1,440	4.2	$36,242
221	with 02HA0RJ, 02HA3RJ or 02HA4RJ	1,681	4.0	$38,175

As with our simulation based on the March 2020 update of the FY 2019 MedPAR file, we believe that this simulation supports that the resulting proposed MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use while at the same time addressing concerns related to the relative weight of MS–DRG 215. A review of this simulation shows that this distribution of ICD–10–PCS codes 02HA0RJ, 02HA3RJ or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device if moved to MS–DRGs 216, 217, 218, 219, 220 and 221, increases the average costs of the cases remaining in MS–DRG 215 by over $6,000, while generally having a more limited effect on the average costs of MS–DRGS 216, 217, 218, 219, 220 and 221.

Therefore, for FY 2022, we are proposing to reassign ICD–10–PCS codes 02HA0RJ, 02HA3RJ, and 02HA4RJ from MDC 05 in MS–DRG 215 to MS–DRGs 216, 217, 218, 219, 220 and 221 in MDC 05.

b. Type II Myocardial Infarction

We received a request to review the MS–DRG assignment of ICD–10–CM diagnosis code I21.A1 (Myocardial infarction type 2). The requestor stated that when a type 2 myocardial infarction is documented, per coding guidelines, it is to be coded as a secondary diagnosis since it is due to an underlying cause. This requestor also noted that when a type 2 myocardial infarction is coded with a principal diagnosis in MDC 05 (Diseases and Disorders of the Circulatory System), the GROUPER logic assigns MS–DRGs 280 through 282 (Acute Myocardial Infarction, Discharged Alive with MCC, with CC, and without CC/MCC, respectively). The requestor questioned if this GROUPER logic was correct or if the logic should be changed so that a type 2 myocardial infarction, coded as a secondary diagnosis, does not result in the assignment of a MS–DRG that describes an acute myocardial infarction.

To begin our analysis, we reviewed the GROUPER logic. The requestor is correct that when diagnosis code I21.A1 is reported as a secondary diagnosis in combination with a principal diagnosis in MDC 05, the case currently groups to medical MS–DRGs 280 through 282 in the absence of a surgical procedure, when the patient is discharged alive. We note that if the patient expires, GROUPER logic instead will assign MS–DRGs 283 through 285 (Acute Myocardial Infarction, Expired with MCC, with CC, and without CC/MCC, respectively) when diagnosis code I21.A1 is reported as a secondary diagnosis in combination with a principal diagnosis in MDC 05.

According to the Universal Definition of Myocardial Infarction (MI), developed by a global task force that included the European Society of Cardiology, the American College of Cardiology, the American Heart Association and the World Heart Federation (WHF), the diagnosis of MI requires the rise and/or fall of cardiac biomarkers with clinical evidence of ischemia in which there is evidence of myocardial injury or necrosis, defined by symptoms, electrocardiographic (ECG) changes, or new regional wall motion abnormalities. Since 2007, this definition further classifies myocardial infarctions into five distinct subtypes. While a type 1 MI is defined as a MI due to an acute coronary syndrome, type 2 MI is defined as a mismatch in myocardial oxygen supply and demand due to other causes such as coronary dissection, vasospasm, emboli, or hypotension that is not attributed to unstable coronary artery disease (CAD).

Our clinical advisors reviewed this issue and do not recommend changing the current MS–DRG assignment of ICD–10–CM diagnosis code I21.A1. As noted by the requestor, the ICD–10–CM Official Guidelines for Coding and Reporting state ''Type 2 myocardial infarction, (myocardial infarction due to demand ischemia or secondary to ischemic imbalance) is assigned to code I21.A1, Myocardial infarction type 2 with a code for the underlying cause coded first.'' Our clinical advisors believe that cases reporting diagnosis code I21.A1 as a secondary diagnosis are associated with a severity of illness on par with cases reporting a principal diagnosis of another type myocardial infarction. They state the diagnosis of myocardial infarction describes myocardial cell death due to inadequate

oxygen supply to the myocardium for a prolonged period, regardless of the subtype. Our clinical advisors state, for clinical consistency, it is more appropriate to maintain the current assignment of ICD–10–CM diagnosis code I21.A1 with the other codes that describe myocardial infarction. Therefore, we are not proposing to reassign diagnosis code I21.A1 from MS–DRGs 280 through 285.

During our review of this issue we noted that code I21.A1 (Myocardial infarction type 2) is currently one of the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock with and without MCC, respectively). However, code I21.A1 is not currently recognized in these same MS–DRGs when coded as a secondary diagnosis. As a result, when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05, MS–DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF, or Shock with and without MCC, respectively) are instead assigned when reported with a listed procedure code. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 38.1, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 222, 223, 224, and 225.

Acknowledging that coding guidelines instruct to code I21.A1 after the diagnosis code that describes the underlying cause, our clinical advisors recommend adding special logic in MS–DRGs 222 and 223 to have code I21.A1 also qualify when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05 since these diagnosis code combinations also describe acute myocardial infarctions.

As a result, we are proposing modifications to the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with a listed procedure code for clinical consistency with the other MS–DRGs describing acute myocardial infarction.

A diagnosis code may define the logic for a specific MS–DRG assignment in three different ways. The diagnosis code may be listed as principal or as any one of the secondary diagnoses, as a secondary diagnosis, or only as a secondary diagnosis as noted in more detail in this proposed rule.

- *Principal or secondary diagnoses.* Indicates that a specific set of diagnoses are used in the definition of the MS–DRG. The diagnoses may be listed as principal or as any one of the secondary diagnoses. A special case of this condition is MS–DRG 008 in which two diagnoses (for example, renal and diabetic) must both be present somewhere in the list of diagnoses in order to be assigned to MS–DRG 008.
- *Secondary diagnoses.* Indicates that a specific set of secondary diagnoses are used in the definition of the MS–DRG. For example, a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839.
- *Only secondary diagnoses.* Indicates that in order to be assigned to the specified MS–DRG no secondary diagnoses other than those in the specified list may appear on the patient's record. For example, in order to be assigned to MS–DRG 795, only secondary diagnoses from the specified list may appear on the patient's record.

We note that whenever there is a secondary diagnosis component to the MS–DRG logic, the diagnosis code can either be used in the logic for assignment to the MS–DRG or to act as a CC/MCC. For this specific scenario, we propose that code I21.A1, as a secondary diagnosis, be used in the definition of the logic for assignment to MS–DRGs 222 and 223, similar to the example described previously, where a secondary diagnosis of acute leukemia with chemotherapy is used to define MS–DRG 839, and therefore will not act as a MCC in these MS–DRGs.

In summary, for FY 2022, we are proposing to maintain the current structure of MS–DRGs 280 through 285. We are also proposing to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

c. Viral Cardiomyopathy

We received three separate but related requests to add ICD–10–CM diagnosis code B33.24 (Viral cardiomyopathy) to the list of principal diagnoses for MS–DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively) in MDC 05. The requestors noted that a discontinuity exists in the current MDC assignment of diagnosis codes in ICD–10–CM subcategory B33.2. The list of the five ICD–10–CM diagnosis codes in subcategory B33.2, as well as their current MDC assignments, is found in the following table.

ICD-10-CM Code	Code Description	MDC
B33.20	Viral carditis, unspecified	05
B33.21	Viral endocarditis	05
B33.22	Viral myocarditis	05
B33.23	Viral pericarditis	05
B33.24	Viral cardiomyopathy	18

A requestor noted ICD–10–CM codes B33.20, B33.21, B33.22, and B33.23 are assigned to MDC 05 (Diseases and Disorders of the Circulatory System), while code B33.24 is assigned to MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites). The requestor stated that the placement of ICD–10–CM diagnosis code B33.24 within subcategory B33.2 is clinically appropriate, as all the diagnoses within this subcategory share a common etiology, involve the heart and supporting structures, and require the same intensity of hospital care. However, the assignment of code B33.24 to a different MDC is clinically incongruous with the placement of the other codes in the subcategory. According to the requestor, all of the conditions share similar etiology, anatomic location, and needs for care, therefore the five codes should all be assigned to MDC 05. This requestor also stated that reassigning code B33.24 to MDC 05 would ensure both clinical continuity and coding consistency within the B33.2 subcategory. Another requestor stated MDC 05 surgical MS–DRGs should be assigned when

procedures such as cardiac catheterization or coronary angioplasty are performed for a principal diagnosis of viral cardiomyopathy.

To begin our analysis, we reviewed the GROUPER logic. Currently, cases reporting ICD–10–CM diagnosis code B33.24 as a principal diagnosis group to medical MS–DRGs 865 and 866 (Viral Illness with and without MCC, respectively) in MDC 18 in the absence of a surgical procedure. Our clinical advisors reviewed this issue and noted viral cardiac infections may present as endocarditis (inflammation of the heart's inner lining), myocarditis (inflammation of the middle layer of the heart), pericarditis (inflammation of the pericardium), or cardiomyopathy (disease of the heart muscle). The infection usually begins somewhere other than the heart, often in the nose, lungs, or stomach. As the infection progresses, and the microbe multiplies and gets into the bloodstream, it can infiltrate the heart muscle. The growth and replication of viruses inside the heart can endanger the heart by destroying heart cells. The management of viral cardiomyopathy is similar to the management of other viral cardiac infections and can include bed rest, control of pain with non-steroidal anti-inflammatory agents and anti-microbial therapy to avoid permanent myocardial damage, cardiomegaly, and/or congestive cardiac failure.

Our clinical advisors agree that the diagnosis of viral cardiomyopathy is clinically related to the other diagnoses in ICD–10–CM subcategory B33.2. They believe it is clinically appropriate for all five diagnoses in subcategory B33.2 to group to MDC 05 (Diseases and Disorders of the Circulatory System) as these conditions describe circulatory system conditions and complications and that this modification will improve clinical coherence. Therefore, we are proposing to reassign ICD–10–CM diagnosis code B33.24 from MDC 18 in MS DRGs 865 and 866 (Viral Illness with and without MCC, respectively) to MDC 05 in MS DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively). Under this proposal, cases reporting procedure codes from MDC 05 in conjunction with principal diagnosis B33.24, would group to MS–DRGs in MDC 05.

d. Left Atrial Appendage Closure (LAAC)

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58471 through 58477), we identified nine ICD–10–PCS procedure codes that describe Left Atrial Appendage Closure (LAAC) procedures and noted their corresponding MS–DRG assignments in the ICD–10 MS–DRGs Version 37 as listed in the following table.

ICD-10-PCS Code	MS-DRG	Description
02L70CK	250-251	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	250-251	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	250-251	Occlusion of left atrial appendage, open approach
02L73CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	273-274	Occlusion of left atrial Appendage with intraluminal device, percutaneous approach
02L73ZK	273-274	Occlusion of left atrial appendage, percutaneous approach
02L74CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	273-274	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	273-274	Occlusion of left atrial appendage, percutaneous endoscopic approach

As discussed in the FY 2021 IPPS/LTCH PPS final rule, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting LAAC procedures with an open approach in MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with and without MCC, respectively). Our analysis showed that the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 had higher average costs and longer average length of stay compared to all cases in MS–DRGs 250 and 251. We also stated our clinical advisors believed that ICD–10–PCS codes 02L70CK, 02L70DK, and 02L70ZK that describe a LAAC procedure with an open approach were more suitably grouped to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectfully). Therefore, we finalized our proposal to reassign ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274. We also finalized a revision to the titles for MS–DRG 273 and 274 to Percutaneous and Other Intracardiac Procedures with and without MCC, respectively to reflect this reassignment for FY 2021.

In response to this final policy, for this FY 2022 IPPS/LTCH PPS proposed rule, we received a request to again review the MS–DRG assignment of cases involving LAAC procedures with an open approach. The requestor disagreed with CMS's FY 2021 IPPS/LTCH PPS final rule decision to move the three procedure codes describing the open occlusion of left atrial appendage to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively). The requestor stated they believe that MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), would more appropriately correspond with the open procedural resources and longer length of stay expected with open heart procedures.

Our clinical advisors reviewed this request and continue to support the reassignment of ICD–10–PCS procedure

codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 to MS–DRGs 273 and 274 because it allows all LAAC procedures to be grouped together under the same MS–DRGs and improves clinical coherence. Our clinical advisors state open LAAC procedures are primarily performed in the absence of another O.R. procedure and generally are not performed with a more intensive open chest procedure. When performed as standalone procedures, open LAAC procedures share similar factors such as complexity and resource utilization with all other LAAC procedures. Our clinical advisors continue to state our FY 2021 final policy results in MS–DRG assignments that are more clinically homogeneous and better reflect hospital resource use. Therefore, we are proposing to maintain the assignment of codes 02L70CK, 02L70DK, and 02L70ZK that describe the open occlusion of the left atrial appendage in MS–DRGs 273 and 274.

e. Surgical Ablation

We received a two-part request to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation. Atrial fibrillation (AF) is an irregular and often rapid heart rate that occurs when the two upper chambers of the heart experience chaotic electrical signals. AF presents as either paroxysmal (lasting <7 days), persistent (lasting >7 days, but less than 1 year), or long standing persistent (chronic) (lasting >1 year) based on time duration and can increase the risk for stroke, heart failure, and mortality. Management of AF has two primary goals: Optimizing cardiac output through rhythm or rate control, and decreasing the risk of cerebral and systemic thromboembolism. Patients that worsen in symptomology or fail to respond to pharmacological treatment or other interventions may be referred for surgical ablation to treat their AF. Surgical ablation is a procedure that works by burning or freezing tissue on the inside of the heart to disrupt faulty electrical signals causing the arrhythmia, which can help the heart maintain a normal heart rhythm.

The first part of this request was to create a new classification of surgical ablation MS–DRGs to better accommodate the costs of open concomitant surgical ablations. According to the requestor, patients undergoing surgical ablation are treated under two potential scenarios: (1) Open concomitant (combination) surgical ablation, meaning open surgical ablation performed during another open-heart surgical procedure such as mitral valve repair or replacement (MVR), aortic valve repair or replacement (AVR), or coronary artery bypass grafting (CABG) and (2) minimally invasive, percutaneous endoscopic, standalone surgical ablation as the sole therapeutic procedure performed. According to the requestor, open concomitant surgical ablation is an efficient procedure, as it allows treatment of AF and another clinical pathology in one procedure thereby decreasing the risk of future readmits, need for future repeat catheter ablation procedures, and patient mortality.

The requestor identified the following potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure.

- Open CABG + open surgical ablation
- Open MVR + open surgical ablation
- Open AVR + open surgical ablation
- Open MVR + open AVR + open surgical ablation
- Open MVR + open CABG + open surgical ablation
- Open MVR + open AVR + open CABG + open surgical ablation
- Open AVR + open CABG + open surgical ablation

The requestor performed its own analysis of these procedure code combinations and stated that it found the average costs for open concomitant surgical ablation procedures were consistently higher compared to the average costs within their respective MS–DRGs, which could limit beneficiary access to these procedures.

The requestor suggested that the following four MS–DRGs be created to address the differences in average costs and average lengths of stay it found in its data analysis:

- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure with Cardiac Catheterization with MCC;
- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure with Cardiac Catheterization without MCC;
- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure without Cardiac Catheterization with MCC; and
- Suggested New MS–DRG XXX—Open Surgical Ablation with or without Other Cardiothoracic Procedure without Cardiac Catheterization without MCC.

In reviewing this request, we identified nine ICD–10–PCS codes that describe open surgical ablation. These codes and their corresponding MDC and MS–DRG assignments are listed in the following table.

ICD-10-PCS Code	MDC	MS-DRG	Description
02540ZZ	05	228-229	Destruction of coronary vein, open approach
02550ZZ	05	228-229	Destruction of atrial septum, open approach
02560ZZ	05	228-229	Destruction of right atrium, open approach
02570ZK	05	250-251	Destruction of left atrial appendage, open approach
02570ZZ	05	228-229	Destruction of left atrium, open approach
02580ZZ	05	228-229	Destruction of conduction mechanism, open approach
02590ZZ	05	228-229	Destruction of chordae tendineae, open approach
025S0ZZ	04 05	163-165 270-272	Destruction of right pulmonary vein, open approach
025T0ZZ	04 05	163-165 270-272	Destruction of left pulmonary vein, open approach

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, for open concomitant surgical ablation procedures, the GROUPER logic assigns MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) in most instances because MS–DRGs 228 and 229 are high in the surgical hierarchy GROUPER logic of MDC 05 (Diseases and Disorders of the Circulatory System). Since patients can have multiple procedures reported with a principal diagnosis during a particular hospital stay, and a patient can be assigned to only one MS–DRG, the surgical hierarchy GROUPER logic provides a hierarchical order of surgical classes from the most resource-intensive to the least resource-intensive. Patients with multiple procedures are generally assigned to the MS–DRG that correlates to the most resource-intensive surgical class.

Our clinical advisors reviewed this grouping issue and noted in open concomitant surgical ablation procedures, the CABG, MVR, and/or AVR components of the procedure are more technically complex than the open surgical ablation procedure. Our clinical advisors stated that in open concomitant surgical ablation procedures, the MS–DRG assigned should be based on the most resource-intensive procedure performed. Therefore, we believe this request would be better addressed by proposing to revise the surgical hierarchy in MDC 05 rather than creating four new MS–DRGs. For FY 2022, we are proposing to revise the surgical hierarchy for the MS–DRGs in MDC 05 to sequence MS–DRGs 231–236 (Coronary Bypass) above MS–DRGs 228 and 229 to enable more appropriate MS–DRG assignment for these types of cases. Under this proposal, if a procedure code describing a CABG and a procedure code describing an open surgical ablation are present, the GROUPER logic would assign the CABG surgical class because a CABG would be sequenced higher in the hierarchy than an open surgical ablation. We refer the reader to section II.D.15. of the preamble of this proposed rule for the discussion of the surgical hierarchy and the complete list of our proposed modifications to the surgical hierarchy in MDC 05.

As mentioned earlier in this section, this request involved two parts. The second part of the request was to reassign cases describing standalone percutaneous endoscopic surgical ablation. According to the requestor, standalone, percutaneous endoscopic surgical ablation is a rapidly growing therapy, indicated for highly symptomatic patients that have already failed medical management and/or percutaneous catheter ablation procedures. The requestor identified nine ICD–10–PCS codes that they stated describe percutaneous endoscopic surgical ablation. These codes and their corresponding MDC and MS–DRG assignments are listed in the following table.

ICD-10-PCS Code	MDC	MS-DRG	Description
02544ZZ	05	228-229	Destruction of coronary vein, percutaneous endoscopic approach
02554ZZ	05	228-229	Destruction of atrial septum, percutaneous endoscopic approach
02564ZZ	05	228-229	Destruction of right atrium, percutaneous endoscopic approach
02574ZK	05	273-274	Destruction of left atrial appendage, percutaneous endoscopic approach
02574ZZ	05	228-229	Destruction of left atrium, percutaneous endoscopic approach
02584ZZ	05	228-229	Destruction of conduction mechanism, percutaneous endoscopic approach
02594ZZ	05	228-229	Destruction of chordae tendineae, percutaneous endoscopic approach
025S4ZZ	04 05	163-165 270-272	Destruction of right pulmonary vein, percutaneous endoscopic approach
025T4ZZ	04 05	163-165 270-272	Destruction of left pulmonary vein, percutaneous endoscopic approach

The requestor performed its own analysis and stated that it found the most common MS–DRG assignment for cases describing standalone percutaneous endoscopic surgical ablation was MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) and that in those MS–DRGs, the standalone surgical ablation procedures cost more than all the procedures in their currently assigned MS–DRGs 228 and 229. Therefore, the requestor recommended CMS reassign these procedures to higher weighted MS–DRGs 219 and 220 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC and with CC, respectively).

We examined claims data from the March 2020 update of the FY 2019 MedPAR file for all cases in MS–DRGs 228 and 229 and compared the results to cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure. Our findings are shown in the following table.

MS-DRGs 228 – 229: Cases Reporting Procedures Describing Percutaneous Endoscopic Surgical Ablation				
MS-DRG	**ICD-10-PCS codes**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
228	All cases	4,436	10.7	$45,772
	Cases with procedure code for percutaneous endoscopic surgical ablation	99	7.1	$48,281
229	All Cases	5,250	5.3	$29,454
	Cases with procedure code for percutaneous endoscopic surgical ablation	497	3.7	$35,516

As shown in the table, the data analysis performed indicates that the 99 cases in MS–DRG 228 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 228 (7.1 days versus 10.7 days) and higher average costs when compared to all the cases in MS–DRG 228 ($48,281 versus $45,772). The 497 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 229 (3.7 days versus 5.8 days) and higher average costs when compared to all the cases in MS–DRG 229 ($35,516 versus $29,454).

We then examined the claims data from the March 2020 update of the FY 2019 MedPAR file to identify the average length of stay and average costs for all cases in MS–DRGs 219 and 220. Our findings are shown in the table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	15,597	10.9	$57,845
220	15,074	6.5	$39,565

As shown in the table, for MS–DRG 219, there were a total of 15,597 cases with an average length of stay of 10.9 days and average costs of $57,845. For MS–DRG 220, there were a total of 15,074 cases with an average length of stay of 6.5 days and average costs of $39,565.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 228 and 229 and compared the results to cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure. Our findings are shown in the following table.

MS-DRGs 228 – 229: Cases Reporting Procedures Describing Percutaneous Endoscopic Surgical Ablation

MS-DRG	ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
228	All cases	4,419	10.2	$46,508
	Cases with procedure code for percutaneous endoscopic surgical ablation	84	6.9	$44,710
229	All Cases	4,732	4.9	$29,885
	Cases with procedure code for percutaneous endoscopic surgical ablation	393	3.4	$34,237

As shown in the table, the data analysis performed indicates that the 84 cases in MS–DRG 228 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 228 (6.9 days versus 10.2 days) and lower average costs when compared to all the cases in MS–DRG 228 ($44,710 versus $46,508). The 393 cases in MS–DRG 229 reporting a procedure code that describes percutaneous endoscopic surgical ablation have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 229 (3.4 days versus 4.9 days) and higher average costs when compared to all the cases in MS–DRG 229 ($34,237 versus $29,885).

We then examined the claims data from the September 2020 update of the FY 2020 MedPAR file to identify the average length of stay and average costs for all cases in MS–DRGs 219 and 220. Our findings are shown in the table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
219	11,863	10.9	$61,934
220	10,072	6.5	$41,800

As shown in the table, for MS–DRG 219, there were a total of 11,863 cases with an average length of stay of 10.9 days and average costs of $61,934. For MS–DRG 220, there were a total of 10,072 cases with an average length of stay of 6.5 days and average costs of $41,800.

Our analysis indicates that MS–DRGs 219 and 220 generally have much higher average costs and longer average lengths of stay than the cases with a procedure code describing a standalone percutaneous endoscopic surgical ablation procedure currently assigned to MS–DRGs 228 and 229. Instead, the average costs and average length of stay for cases reporting a standalone percutaneous endoscopic surgical ablation appear to be generally more aligned with the average costs and average length of stay for all cases in MS–DRGs 228 and 229, where they are currently assigned. Our clinical advisors reviewed this issue and do not recommend changing the assignment of procedure codes describing percutaneous endoscopic surgical ablation. Therefore, for these reasons, we are proposing to maintain the current structure of MS–DRGs 219 and 220.

f. Drug-Eluting Stents

We received a request to review the MS–DRG assignments of claims involving the insertion of coronary stents in percutaneous coronary interventions. The requestor suggested that CMS eliminate the distinction between drug-eluting and bare-metal coronary stents in the MS–DRG classification. According to the requestor, coated stents have a clinical performance comparable to drug-eluting stents however they are grouped with bare-metal stents because they do not contain a drug. The requestor asserted that this comingling muddies the

clinical coherence of the MS–DRG structure, as one cannot infer distinctions in clinical performance or benefits among the groups and potentially creates a barrier (based on hospital decision-making) to patient access to modern coated stents.

The requestor listed the following MS–DRGs in its request.

- MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents);
- MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC);
- MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents); and
- MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC).

According to the requestor, the non-drug-eluting stent MS–DRGs have outlived their usefulness in the stent market. The requestor performed its own analysis of MedPAR data from FY 2015 through FY 2019 and stated that it found the volume of cases describing non-drug-eluting coronary stents has declined since 2015, culminating in FY 2019, with drug-eluting stents accounting for 96.1% of all stent cases within the Medicare program, while non-drug-eluting stents accounted for only 3.9% that year. The requestor asserted that the assignment of coated stents to the non-drug-eluting stent category creates a market distortion as this newer technology is being comingled with very old technology at a payment disadvantage large enough to influence hospitals' willingness to prescribe, while at the same time acknowledging that the separation in average charges and costs between the non-drug-eluting stent category and the drug-eluting stent category is minimal in their analysis of the claims data.

Based on a review of the procedure codes that are currently assigned to MS–DRGs 246, 247, 248 and 249, our clinical advisors agree that further refinement of these MS–DRGs may be warranted. However, in ICD–10–PCS, a stent is considered an intraluminal device. The distinction between drug-eluting and non-drug eluting intraluminal devices is found elsewhere in the ICD–10–PCS procedure code classification and evaluating this request requires a more extensive analysis to assess potential impacts across the MS–DRGs. For these reasons, at this time, our clinical advisors recommend that rather than evaluating the procedure codes assigned to MS–DRGs 246, 247, 248 and 249 in isolation, additional analysis should be performed for this subset of procedure codes across the MS–DRGs, as part of the comprehensive procedure code review described in section II.D.11. of the preamble of this proposed rule. Therefore, we believe it would be more appropriate to consider this request further during our comprehensive procedure code review in future rulemaking.

6. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Knee Joint Procedures

We received a request to examine the procedure code combinations for procedures describing a right knee joint removal and replacement and procedures describing a left knee joint removal and replacement in MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively). According to the requestor, when using the MS–DRG GROUPER software version 37, the left knee joint procedure combinations group correctly to MS–DRG 468, while the exact same right knee procedure code combinations group incorrectly to MS–DRG 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC).

The requestor provided the following procedure codes that describe the procedure code combinations for the left knee joint removal and replacement procedures currently assigned to MS–DRGs 466, 467, and 468.

ICD-10-PCS Code	Description	*with*	ICD-10-PCS Code	Description
0SPD4JC	Removal of synthetic substitute from left knee joint, patellar surface, percutaneous endoscopic approach	*with*	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach
0SPU4JZ	Removal of synthetic substitute from left knee joint, femoral surface, percutaneous endoscopic approach	*with*	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach
0SPW4JZ	Removal of synthetic substitute from left knee joint, tibial surface, percutaneous endoscopic approach	*with*	0SRW0JZ	Replacement of left knee joint, tibial surface with synthetic substitute, open approach

The requestor also provided the following procedure codes that describe the procedure code combinations for right knee joint removal and replacement procedures for CMS's review and consideration.

ICD-10-PCS Code	Description	*with*	ICD-10-PCS Code	Description
0SPC4JC	Removal of synthetic substitute from right knee joint, patellar surface, percutaneous endoscopic approach	*with*	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPT4JZ	Removal of synthetic substitute from right knee joint, femoral surface, percutaneous endoscopic approach	*with*	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach
0SPV4JZ	Removal of synthetic substitute from right knee joint, tibial surface, percutaneous endoscopic approach	*with*	0SRV0JZ	Replacement of right knee joint, tibial surface with synthetic substitute, open approach

We reviewed the procedure code combinations listed and agree with the requestor that the procedure codes that describe the procedure code combinations for right knee joint removal and replacement procedures were inadvertently excluded from the logic for MS–DRGs 466, 467, and 468.

During our review of the previously listed procedure code combinations describing removal and replacement of the right and left knee joints, we identified additional MS–DRGs in which the listed procedure code combinations for the left knee joint are in the logic, however, the listed procedure code combinations for the right knee joint were inadvertently excluded from the logic. Specifically, the listed procedure code combinations describing removal and replacement of the left knee joint are also included in the logic for case assignment to MS–DRGs 461 and 462 (Bilateral or Multiple Major Joint Procedures of Lower Extremity with and without MCC, respectively) in MDC 08 and in the logic for case assignment to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders). Our clinical advisors stated that the procedure code combinations describing removal and replacement of the right knee joint should be added to MS–DRGs 461, 462, 466, 467, and 468 in MDC 08 and MS–DRGs 628, 629, and 630 in MDC 10 for consistency with the procedure code combinations describing removal and replacement of the left knee joint that are currently assigned to those MS–DRGs. Adding these procedure codes will improve clinical coherence and ensure more appropriate MS–DRG assignment for these cases.

Therefore, for FY 2022, we are proposing to add the three procedure code combinations listed previously describing removal and replacement of the right knee joint that were inadvertently omitted from the logic to MS–DRGs 461, 462, 466, 467, and 468 in MDC 08 and MS–DRGs 628, 629, and 630 in MDC 10.

b. Pelvic Trauma With Internal Fixation

We received a request to reassign cases reporting a diagnosis code describing a pelvic fracture in combination with a procedure code describing repair of a pelvic fracture with internal fixation, from the lower (NonCC) severity level MS–DRG of its current base MS–DRG assignment to the higher (MCC) severity level MS–DRG of its current base MS–DRG assignment. According to the requestor, there has been steady growth in the volume of internal fixation procedures performed for pelvic fractures since 2008. The requestor stated that due to this growth rate and the anticipated increase in utilization of these internal fixation devices in these procedures in the future that CMS should reconsider the payment structure for these cases it referred to as ''internal fixation for pelvic trauma''.

The requestor provided data for the Healthcare Common Procedural Coding System (HCPCS) code G0413 (Percutaneous skeletal fixation of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, (includes ileum, sacroiliac joint and/or sacrum) and current procedural terminology (CPT) code 22848 (Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum) from 2008 through 2018 that it crosswalked to ICD–10–PCS procedure codes. The requestor stated that this CPT coded data indicated that physicians have used pelvic fracture fixation, and pelvic instrumentation, for an increasing number of trauma/fracture repair cases, demonstrating expanded use of these devices in the pelvic area overall.

The requestor reported that sacral fractures are often underdiagnosed and once the diagnosis is made, bedrest is common, although prolonged bedrest is not recommended for the elderly. In addition, the requestor stated that pelvic fractures may be isolated or they may be associated with surrounding structures. For example, the requester reported that the sacroiliac joint is involved in approximately 30 to 35% of pelvic fracture cases. According to the requestor, the standard of care has also transitioned, from bedrest-only to surgery, and current medical practice has evolved to lower the threshold for fracture repair surgery. For instance, the requestor stated that smaller 5mm

fractures that were once left untreated now have standard treatment protocols involving the use of pelvic instrumentation. As a result, the requestor asserted that there will be greater utilization of internal fixation devices to treat these smaller pelvic fractures.

The requestor provided the following procedure codes that it stated describe procedures involving the use of internal fixation devices for pelvic fracture repair.

ICD-10-PCS Code	Description
0QS204Z	Reposition right pelvic bone with internal fixation device, open approach
0QS234Z	Reposition right pelvic bone with internal fixation device, percutaneous approach
0QS304Z	Reposition left pelvic bone with internal fixation device, open approach
0QS334Z	Reposition left pelvic bone with internal fixation device, percutaneous approach
0SG704Z	Fusion of right sacroiliac joint with internal fixation device, open approach
0SG734Z	Fusion of right sacroiliac joint with internal fixation device, percutaneous approach
0SG804Z	Fusion of left sacroiliac joint with internal fixation device, open approach
0SG834Z	Fusion of left sacroiliac joint with internal fixation device, percutaneous approach

The requestor also provided the following diagnosis code subcategories that it stated identify diagnoses describing pelvic fracture.

ICD-10-CM Subcategory	Description
S32.1 -	Fracture of sacrum
S32.2 -	Fracture of coccyx
S32.3 -	Fracture of ilium

The requestor performed its own analysis of claims data and reported findings for cases reporting a combination of the diagnosis codes found in the listed diagnosis code subcategories and the listed procedure codes (internal fixation for pelvic trauma) for MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively). According to the requestor, its findings support reassignment of these internal fixation for pelvic trauma cases from the lower severity level MS–DRG 517 to the higher severity level MS–DRG 515, from the lower severity level MS–DRG 909 to the higher severity level 907, and from the lower severity level MS–DRG 959 to the higher severity level 957. The requestor suggested that approximately 2,000 cases would be impacted by its recommendation to reassign internal fixation for pelvic trauma cases. The requestor also stated that these internal fixation for pelvic trauma cases currently result in a high rate of CMS outlier payments to institutions that perform a high volume of these procedures. Finally, the requestor stated that there is precedent for reassignment of cases from the lower severity level MS–DRGs to the higher severity level MS–DRG for cases involving the use of a device in orthopedic surgery. The requestor provided the examples of total ankle replacement procedures, spinal disc replacement procedures and neurostimulator implantation procedures to demonstrate how CMS has previously reassigned cases from the lower severity level MS–DRG to the higher severity level MS–DRG.

We first examined the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for all cases in MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959. Our findings are shown in the following tables.

March 2020 Update of the FY 2019 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515 – All cases	4,831	8.2	$22,403
516 – All cases	14,089	4.6	$14,310
517 – All cases	12,675	2.6	$10,316
907 – All cases	10,342	9.6	$28,037
908 – All cases	9,129	5.2	$14,681
909 – All cases	2,994	2.9	$10,078
957 – All cases	2,325	13.1	$54,500
958 – All cases	1,845	8.2	$30,973
959 – All cases	130	5.1	$20,204

September 2020 Update of the FY 2020 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515 – All cases	3,691	8.0	$23,094
516 – All cases	10,582	4.6	$15,308
517 – All cases	8,203	2.6	$11,301
907 – All cases	8,706	9.2	$28,127
908 – All cases	7,434	5.1	$15,222
909 – All cases	2,080	2.8	$10,650
957 – All cases	2,028	12.9	$56,366
958 – All cases	1,500	7.9	$32,638
959 – All cases	126	4.7	$18,423

We then examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting any combination of the diagnosis and procedure codes that the requestor provided to identify internal fixation for pelvic trauma cases in MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959.

We note that our analysis identified two types of cases in which the combination of a diagnosis code and a procedure code (that the requestor provided to identify internal fixation for pelvic trauma cases) was reported. The first type of case consisted of a diagnosis code describing a pelvic fracture reported in combination with a single procedure code describing repair of a pelvic fracture with internal fixation on a claim, and the second type of case consisted of a diagnosis code describing a pelvic fracture reported in combination with two procedure codes describing repair of a pelvic fracture with internal fixation (for example, one for the right side and one for the left side) on a claim. These cases are described as single and bilateral internal fixation procedures for pelvic trauma, respectively. We refer the reader to Tables 6P.1h and 6P.1i associated with this proposed rule (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of diagnosis and procedure code combinations reflecting single internal fixation for pelvic trauma procedures reported by case ID in each MS–DRG, by fiscal year, along with the detailed claims analysis. We refer the reader to Tables 6P.1j and 6P.1k associated with this proposed rule (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of diagnosis and procedure code combinations reflecting bilateral internal fixation for pelvic trauma procedures reported by case ID in each MS–DRG, by fiscal year, along with the detailed claims analysis. For example, Table 6P.1h shows the claims data analysis findings from the March 2020 update of the FY 2019 MedPAR file. Line 2 identifies the section for single cases reported in MS–DRG 515, line 13 identifies the section for single cases reported in MS–DRG 516, and line 42 identifies the single cases reported in MS–DRG 517. The following table summarizes the information found in each column of the tables.

Column	Description
A	Case ID (identification) assigned
B	MS-DRG
C	ICD-10-CM code reported as the principal diagnosis
D	Description of the ICD-10-CM diagnosis code
E	ICD-10-PCS code reported for procedure
F	Description of the ICD-10-PCS procedure code
G	Case count
H	Average length of stay for case in days
I	Average costs for case
J	Frequency of procedure reported for case
K	Length of stay for case in days
L	Cost of case

As shown in Table 6P.1h, line 4, column A, displays the Case ID ''Single-A'' for the first case; column B displays MS–DRG 515; column C displays the diagnosis code S32.111A; column D displays the description of the diagnosis code (Minimally displaced Zone 1 fracture of sacrum, initial encounter for closed fracture); column E displays the procedure code 0QS234Z; column F displays the description of the procedure code (Reposition right pelvic bone with internal fixation device, percutaneous approach); column G displays the case count 1; column H displays an average length of stay of 3.0 days; column I displays average costs of $8,433 for the case; column J displays the frequency of the procedure reported was one (1) occurrence; column K displays a 3.0 day length of stay for the case; and column L displays $8,433 for the cost of the case.

In our analysis of the claims data from the March 2020 update of the FY 2019 MedPAR file, we found that there were no cases reporting any combination of the diagnosis codes and procedure codes previously listed in MS–DRGs 907, 908, and 909 or MS–DRGs 957, 958, and 959. Our findings are shown in the following table for any cases found to report a diagnosis code describing a pelvic trauma in combination with a procedure code describing single internal fixation in MS–DRGs 515, 516, and 517.

March 2020 Update of the FY 2019 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515 – All cases	4,831	8.2	$22,403
515 – Cases with single internal fixation for pelvic trauma	6	5.67	$28,368
516 – All cases	14,089	4.6	$14,310
516 – Cases with single internal fixation for pelvic trauma	20	5.8	$12,879
517 – All cases	12,675	2.6	$10,316
517 – Cases with single internal fixation for pelvic trauma	3	5.33	$12,147

As shown in the table, there were only three cases found in MS–DRG 517 reporting single internal fixation for pelvic trauma procedures, with an average length of stay of 5.33 days and average costs of $12,147. The average length of stay is longer and the average costs of these three cases higher compared to the average length of stay and the average costs for all cases in MS–DRG 517 (5.33 days versus 2.6 days and $12,147 versus $10,316, respectively); however, overall, we believe the data findings are comparable. Our clinical advisors did not support reassignment of the three cases from MS–DRG 517 to MS–DRG 515 based on the claims data analysis and also stated it would not be appropriate to reassign these cases into the higher severity level MS–DRG in the absence of a MCC and noted that the cases would not be clinically coherent with regard to resource utilization.

In our analysis of the claims data from the March 2020 update of the FY 2019 MedPAR file for cases in which a bilateral internal fixation for pelvic trauma procedure was performed, we identified one case in MS–DRG 517. As shown in Table 6P.1j, the average length of stay for this case was 4.0 days and the average costs were $24,258, which is longer than the average length of stay and greater than the average costs for all cases in MS–DRG 517 (2.6 days and $10,316, respectively). We also identified cases reporting various code combinations for MS–DRGs 515 and 516, and provide the details in Table 6P.1j associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

In our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file we found that there were no cases reporting any combination of the diagnosis codes and procedure codes previously listed in MS–DRG 909 or in MS–DRGs 957, 958, and 959. Our findings are shown in the following table for any cases found to report a diagnosis code describing a pelvic trauma in combination with a procedure code describing single internal fixation in MS–DRGs 515, 516, 517, 907, and 908.

September 2020 Update of the FY 2020 MedPAR File			
MS-DRG	**Number of cases**	**Average Length of Stay**	**Average Costs**
515- All cases	3,691	8.0	$23,094
515 - Cases with single internal fixation for pelvic trauma	6	8.3	$17,356
516 - All cases	10,582	4.6	$15,308
516 - Cases with single internal fixation for pelvic trauma	20	4.35	$14,163
517- All cases	8,203	2.6	$11,301
517 - Cases with single internal fixation for pelvic trauma	4	2.5	$10,136
907 - All cases	8,706	9.2	$28,127
907 - Cases with single internal fixation for pelvic trauma	1	25.0	$97,152
908 - All cases	7,434	5.1	$15,222
908 - Cases with single internal fixation for pelvic trauma	1	6.0	$19,741

As shown in the table, there were only four cases found in MS–DRG 517 reporting single internal fixation for pelvic trauma procedures, with an average length of stay of 2.5 days and average costs of $10,136. For the same reasons described previously based on the FY 2019 analysis, our clinical advisors did not support reassignment of the cases in the lower severity level MS–DRG 517 to the higher severity level MS–DRG 515. In addition, the average length of stay and average costs for these four cases reporting single internal fixation for pelvic trauma procedures are less than the average length of stay and average costs for all the cases in MS–DRG 517 (2.5 days versus 2.6 days and $10,136 versus $11,301, respectively)); however, overall, we believe the data findings are comparable.

In our analysis of the claims data from the September 2020 update of the FY 2020 MedPAR file for cases in which a bilateral internal fixation for pelvic trauma procedure was performed, we identified one case in MS–DRG 517. As shown in Table 6P.1k, the average length of stay for this case was 2.0 days and the average costs were $10,103, which is shorter than the average length of stay and less than the average costs for all cases in MS–DRG 517 (2.6 days and $11,301, respectively). We also identified cases reporting various combinations for MS–DRGs 515, 516 and MS–DRG 907, and provide the details in Table 6P.1k associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*).

We believe further analyses of these internal fixation for pelvic trauma cases in the claims data is warranted. We note that our analysis for both the single and bilateral cases was centered on the reporting of a principal diagnosis code describing a pelvic trauma (fracture) in combination with a procedure code describing internal fixation based on the codes provided by the requestor. However, we also identified cases in the claims data in which a pelvic trauma diagnosis code was reported as a secondary diagnosis code in combination with a procedure code describing internal fixation and believe these cases require further evaluation. In addition, during our review of the diagnosis and procedure codes that the requestor provided, we identified diagnosis codes that we believe do not warrant consideration for purposes of this request and additional procedure codes that describe internal fixation for pelvic trauma procedures, which we believe do warrant further analysis. For example, as previously noted, the requestor provided the subcategories for

the diagnosis codes that it requested we consider for analysis. We do not agree that diagnosis codes describing a pelvic fracture that include the term ''sequela'' should be considered in the analysis to examine this request because, in the ICD–10–CM classification, the term sequela is defined as the residual effect (condition produced) after the acute phase of an illness or injury has terminated.

We refer the reader to Table 6P.1g for the list of diagnosis codes that are included in the diagnosis subcategories provided by the requestor and the list of procedure codes provided by the requestor, which also contains the procedure codes we identified. Additional time is needed for data analysis given the volume of these code combinations and corresponding data. We also believe that additional time is needed to allow for further analysis of the claims data to determine the causes of the fractures and other possible contributing factors with respect to the length of stay and costs of these cases, as well as the rate of outlier payments as identified by the requestor. Our clinical advisors also believe that future data findings may demonstrate additional variance in resource utilization for this patient population. We further note that, as discussed in the FY 2021 IPPS/LTCH PPS final rule, we finalized the addition of 161 procedure codes to MS–DRGs 957, 958, and 959 in MDC 24 (Multiple Significant Trauma) that include the insertion of internal fixation devices. We believe it would be beneficial to examine future claims data to determine if there is a change in the volume of cases in those specific MS–DRGs as a result of that update. For these reasons, we are proposing to maintain the structure of MS–DRGs 515, 516, and 517; MS–DRGs 907, 908, and 909; and MS–DRGs 957, 958, and 959 for FY 2022.

7. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Chronic Renal Replacement Therapy (CRRT)

We received a request to create new MS–DRGs for cases where the patient receives continuous renal replacement therapy (CRRT) during the inpatient stay. According to the requestor, hospitals incur higher costs related to CRRT and current MS–DRG definitions do not adequately account for the clinical and resource requirements of CRRT. The requestor stated Medicare reimbursement is insufficient to cover the costs of administering CRRT, creating a disincentive in offering this dialysis modality and is a barrier to further adoption of CRRT. The requestor suggested that the following two new MS–DRGs be created:

- Suggested New MS–DRG XXX—Continuous Renal Replacement Therapy with CC/MCC; and
- Suggested New MS–DRG XXX—Continuous Renal Replacement Therapy without CC/MCC.

Renal replacement therapy (RRT) replaces kidney function by exchanging solute and removing fluid from the blood as a means to prevent or treat renal failure in patients with acute kidney injury (AKI). Modalities of renal support include CRRT, conventional intermittent hemodialysis (IHD), and prolonged intermittent renal replacement therapies (PIRRTs), which are a hybrid of CRRT and IHD. IHD provides solute clearance and filtration during relatively brief treatment sessions, generally lasting from three to five hours. CRRT provides gradual fluid removal and solute clearance over prolonged treatment times, typically over a 24-hour period, mimicking the natural function of the kidney to allow for the continuous removal or replacement of fluid. The most common CRRT modalities are continuous venovenous hemofiltration, continuous venovenous hemodialysis, and continuous venovenous hemodiafiltration.

According to the requestor, CRRT is used primarily to treat critically ill, hospitalized patients who experience AKI requiring more intensive and continuous treatment than other dialysis modalities. The requestor stated that CRRT offers fluid balance and convective clearance that may be precisely adjusted for each patient, and has been associated with a higher likelihood of kidney recovery as compared to other modalities of RRT. The requestor asserted that IHD may worsen the neurological status of patients with acute brain injury or other causes of increased intracranial pressure by compromising their cerebral perfusion by raising intracranial pressure. The ongoing modulation of fluid balance and targeted fluid management capabilities of CRRT enables its use in situations other than renal failure. According to the requestor, CRRT, a slow continuous therapy, is preferred for patients who are hemodynamically unstable because it helps prevent the hemodynamic fluctuations common with the more rapid IHD. In light of the COVID–19 pandemic, the requestor noted the National Institutes of Health's Coronavirus Disease 2019 (COVID–19) Treatment Guidelines and The American Society of Nephrology recommend CRRT as the preferred renal replacement therapy for critically ill, COVID–19 patients experiencing AKI, who develop indications for renal replacement therapy, due to the hemodynamic instability often experienced in this condition.

The requestor acknowledged that under the current MS–DRG definitions, Medicare cases with beneficiaries receiving CRRT are assigned to more than 300 MS–DRGs. Although these beneficiaries are clinically similar in that they are critically ill patients who experience AKI requiring more intensive and continuous treatment than other dialysis modalities, the principal diagnoses for their inpatient stays vary. The requestor stated their analysis of the variability in principal diagnosis of the cases examined with beneficiaries receiving CRRT indicated that, in general, IHD tends to be used more for patients with chronic illnesses, and CRRT tends to be used for more acute injuries and end of life scenarios. Therefore, the requestor suggested that CMS create new MS–DRGs specific to CRRT, without regard to principal diagnosis, in order to group the resource intensive, clinically coherent, CRRT cases together in contrast to the existing GROUPER definitions.

According to the requestor, continuing to assign CRRT to existing MS–DRGs would be clinically inappropriate and remain financially devastating to providers even when treating the most routine, uncomplicated CRRT patients. The requestor performed its own data analysis and stated hospitals lose over $22,000 per CRRT case on average, even when outliers are considered, which they state is a shortfall of more than 30 percent. The requestor asserted these losses create a disincentive for providers to offer CRRT despite its clinical benefits. The requestor also asserted the magnitude of financial losses associated with the provision of CRRT at the current level of MS–DRG payment could force many hospitals to examine the capacity and scope of their CRRT programs if facilities continue to determine that the financial burden of treating Medicare beneficiaries with CRRT is more than the facility can sustain. As COVID–19 continues to strain hospital resources, the requestor asserts the availability of CRRT should not be impeded by inadequate MS–DRG payments related to CRRT.

The following ICD–10–PCS procedure code identifies the performance of CRRT.

ICD-10-PCS Code	Code Description
5A1D90Z	Performance of urinary filtration, continuous, greater than 18 hours per day

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure code 5A1D90Z is currently recognized as a non-O.R. procedure that affects the MS–DRG to which it is assigned. Our clinical advisors agree that the principal diagnosis assigned for inpatient admissions where continuous renal replacement of therapy is utilized can vary. To examine the impact of the use of CRRT, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for the top ten MS–DRGs reporting the use of CRRT. Our findings are reflected in the following table:

Top 10 MS-DRGs Reporting Continuous Renal Replacement Therapy					
MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	609,320	6.2	$13,338
		Cases with CRRT	2,912	7.9	$27,681
870	Septicemia Or Severe Sepsis with MV >96 Hours	All cases	32,497	14.5	$44,878
		Cases with CRRT	1,731	15.9	$60,478
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC	All cases	85,196	12.5	$34,178
		Cases with CRRT	1,470	17.4	$69,966
003	ECMO or Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	All cases	14,532	30.2	$128,196
		Cases with CRRT	1,459	33.4	$174,085
291	Heart Failure and Shock with MCC	All cases	394,415	5.1	$9,668
		Cases with CRRT	660	11.9	$34,628
004	Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures	All cases	12,702	24.5	$77,393
		Cases with CRRT	463	35.5	$138,940
207		All cases	18,412	14	$39,929

Top 10 MS-DRGs Reporting Continuous Renal Replacement Therapy					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
	Respiratory System Diagnosis with Ventilator Support >96 Hours	Cases with CRRT	458	16.8	$61,632
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	All cases	15,597	10.9	$57,845
		Cases with CRRT	442	17.1	$98,802
270	Other Major Cardiovascular Procedures with MCC	All cases	18,959	9.5	$37,249
		Cases with CRRT	430	14.8	$70,030
682	Renal Failure with MCC	All cases	103,511	5.7	$10,486
		Cases with CRRT	401	9.8	$29,089

As shown in this table, our data findings demonstrate the average lengths of stay were longer and the average costs were higher for the cases reporting the use of CRRT when compared to all cases in their respective MS–DRG. We note that the claims data demonstrate that the MS–DRG with the largest number of cases reporting CRRT is MS–DRG 871 with 2,912 cases. Of the top 10 MS–DRGs reporting CRRT, the MS–DRG with the smallest number of cases is MS–DRG 682 with 401 cases. The average length of stay of this subset of cases ranges from a high of 35.5 days in MS–DRG 004 to a low of 7.9 days in MS–DRG 871 for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $174,085 in MS–DRG 003 to a low of $27,681 in MS–DRG 871 for cases reporting the use of CRRT.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for the top ten MS–DRGs reporting the use of CRRT. Our similar findings are reflected in the following table:

Top 10 MS-DRGs Reporting Continuous Renal Replacement Therapy					
MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	552,641	6.4	$14,140
		Cases with CRRT	3,023	7.9	$29,248
870	Septicemia Or Severe Sepsis with MV >96 Hours	All cases	40,079	15.2	$48,909
		Cases with CRRT	2,480	16.7	$66,120
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC	All cases	78,586	12.3	$35,594
		Cases with CRRT	1,464	17.1	$71,270
003	ECMO or Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures	All cases	11,768	30.9	$137,021
		Cases with CRRT	1,338	34	$182,952
207	Respiratory System Diagnosis with Ventilator Support >96 Hours	All cases	24,106	15.8	$47,379
		Cases with CRRT	976	18.7	$68,254
004	Tracheostomy with MV >96 hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures	All cases	12,248	26.4	$88,922
		Cases with CRRT	600	34.9	$134,323
291	Heart Failure and Shock with MCC	All cases	313,097	5.1	$10,055
		Cases with CRRT	594	10.7	$33,604
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours	All cases	50,397	6.9	$19,519
		Cases with CRRT	496	8.6	$31,853
270	Other Major Cardiovascular Procedures with MCC	All cases	16,764	9.3	$39,520
		Cases with CRRT	416	14.3	$68,957
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	All cases	11,863	10.9	$61,934
		Cases with CRRT	374	18.7	$108,744

As shown in this table, our data findings show that the average lengths of stay were longer and the average costs were higher for the cases reporting the use of CRRT when compared to all cases in their respective MS–DRG. We note that the claims data demonstrate that the MS–DRG with the largest number of cases reporting CRRT is MS–DRG 871 with 3,023 cases. Of the top 10 MS–DRGs reporting CRRT, the MS–DRG with the smallest number of cases is MS–DRG 219 with 374 cases. The average length of stay of this subset of cases ranges from a high of 34.9 days in MS–DRG 004 to a low of 7.9 days in MS–DRG 871 for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $182,952 in MS–DRG 003 to a low of $29,248 in MS–DRG 871 for cases reporting the use of CRRT.

While the results of the claims analysis indicate that the average costs and average lengths of stay for cases reporting the use of CRRT are higher compared to the average costs for all cases in their assigned MS–DRG, we are unable to ascertain from the claims data the resource use specifically attributable to CRRT during a hospital stay. There is large variability in the differences in average costs from MS–DRG to MS–DRG, indicating there may have been other factors contributing to the higher costs. When reviewing consumption of hospital resources for this subset of cases, the claims data clearly demonstrate the patients typically have a major complication or co-morbid (MCC) condition reported based on the MS–DRGs assigned. The claims data also reflects, based on the top ten MS–DRGS, that the procedure frequently occurs in cases with other procedures with higher than average resource use such as mechanical ventilation, tracheostomy, extracorporeal membrane oxygenation (ECMO) and other major cardiovascular procedures that also may be contributing to the higher average costs for these cases.

To further examine the variability in cases reporting the use of CRRT, we also reviewed the claims data to identify the number (frequency) and types of principal diagnoses that were reported to determine what factors may also be contributing to the higher average costs for these cases.

Our findings for the top 10 principal diagnoses that were reported within the claims data from the March 2020 update of the FY 2019 MedPAR file for this subset of cases is shown in the following table:

Top 10 Principal Diagnoses Reported with the Procedure Code for Continuous Renal Replacement Therapy				
ICD-10-CM Code	**Description**	**Number of Times Reported**	**Average Length of Stay**	**Average Costs**
A41.9	Sepsis, unspecified organism	4,226	12.6	$48,150
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	691	16.5	$85,557
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	652	20	$81,401
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	551	17.6	$60,493
A41.51	Sepsis due to Escherichia coli [E. coli]	459	14.7	$54,643
J96.01	Acute respiratory failure with hypoxia	346	13.2	$50,227
N17.9	Acute kidney failure, unspecified	319	13.8	$40,908
N17.0	Acute kidney failure with tubular necrosis	307	14.3	$41,196
A41.59	Other Gram-negative sepsis	273	17.4	$67,917
A41.01	Sepsis due to Methicillin susceptible Staphylococcus aureus	271	17.1	$62,664

The claims data in this table reflects a wide variance with regard to the frequency and types of principal diagnoses that were reported along with the procedure code describing the use of CRRT. We note that the claims data demonstrate that the diagnosis with the largest number of cases reporting CRRT is A41.9 (Sepsis, unspecified organism) with 4,226 cases. Of the top 10 principal diagnoses reporting CRRT, the diagnosis with the smallest number of cases is A41.01 (Sepsis due to Methicillin susceptible Staphylococcus aureus) with 271 cases. The average length of stay of this subset of cases ranges from a high of 20 days with a diagnosis of I13.0 (Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) to a low of 12.6 days with a diagnosis of A41.9 (Sepsis, unspecified organism) for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $85,557 with a diagnosis of I21.4 (Non-ST elevation (NSTEMI) myocardial infarction) to a low of $40,908 with a diagnosis of N17.9 (Acute kidney failure, unspecified) for cases reporting the use of CRRT.

Our findings for the top 10 principal diagnoses that were reported within the claims data from the September 2020 update of the FY 2020 MedPAR file for this subset of cases is shown in the following table:

Top 10 Principal Diagnoses Reported with the Procedure Code for Continuous Renal Replacement Therapy				
ICD-10-CM Code	**Description**	**Number of Times Reported**	**Average Length of Stay**	**Average Costs**
A41.9	Sepsis, unspecified organism	4,128	12.5	$51,228
A41.89	Other specified sepsis	1,302	18.8	$76,519
U07.1	COVID-19	868	21.4	$79,721
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	650	16.6	$86,717
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	618	19	$77,404
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	532	16.3	$59,959
A41.51	Sepsis due to Escherichia coli [E. coli]	437	15.6	$58,858
J96.01	Acute respiratory failure with hypoxia	340	11.8	$48,882
A41.59	Other Gram-negative sepsis	295	16.5	$65,951
N17.0	Acute kidney failure with tubular necrosis	270	16.2	$49,577

The claims data in this table also reflects a wide variance with regard to the frequency and types of principal diagnoses that were reported along with the procedure code describing the use of CRRT. As shown, the claims data demonstrate that the diagnosis with the largest number of cases reporting CRRT is A41.9 (Sepsis, unspecified organism) with 4,128 cases. Of the top 10 principal diagnoses reporting CRRT, the diagnosis with the smallest number of cases is N17.0 (Acute kidney failure with tubular necrosis) with 270 cases. The average length of stay of this subset of cases ranges from a high of 21.4 days with a diagnosis of U07.1 (COVID–19) to a low of 11.8 days with a diagnosis of J96.01 (Acute respiratory failure with hypoxia) for cases reporting the use of CRRT. The average costs of this subset of cases ranges from a high of $ 86,717 with a diagnosis of I21.4 (Non-ST elevation (NSTEMI) myocardial infarction) to a low of $ 48,882 with a diagnosis of J96.01 (Acute respiratory failure with hypoxia) for cases reporting the use of CRRT.

To evaluate the frequency with which the use of CRRT is reported for different clinical scenarios, we examined claims from the March 2020 update of the FY 2019 MedPAR file across each of the 25 MDCs to determine the number of cases reporting the use of CRRT. Our findings are shown in this table.

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Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases with CRRT	19,608	16.5	$68,592
MDC 01 (Diseases and Disorders of the Nervous System)--Cases with CRRT	558	17.5	$64,523
MDC 02 (Disease and Disorders of the Eye)--Cases with CRRT	5	15.4	$36,053
MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)--Cases with CRRT	23	17.4	$65,221
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases with CRRT	1,370	17.8	$72,158
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases with CRRT	6,027	17.9	$86,024
MDC 06 (Diseases and Disorders of the Digestive System)--Cases with CRRT	987	18.8	$73,408
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases with CRRT	870	20.9	$87,272
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases with CRRT	412	18.2	$69,621
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases with CRRT	72	14.5	$43,633
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)--Cases with CRRT	383	11.8	$41,559
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases with CRRT	1,134	15.4	$48,276
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases with CRRT	9	17.3	$55,931

Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 13 (Diseases and Disorders of the Female Reproductive System)--Cases with CRRT	15	47.3	$131,252
MDC 14 (Pregnancy, Childbirth and the Puerperium)--Cases with CRRT	3	8	$22,852
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases with CRRT	134	21.8	$78,138
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases with CRRT	260	25.8	$95,309
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases with CRRT	6,761	14.1	$54,051
MDC 19 (Mental Diseases and Disorders)--Cases with CRRT	5	13.8	$30,664
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)--Cases with CRRT	5	15.4	$39,332
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases with CRRT	390	16.3	$61,846
MDC 22 (Burns)--Cases with CRRT	27	19	$104,749
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)--Cases with CRRT	13	15.6	$36,295
MDC 24 (Multiple Significant Trauma)--Cases with CRRT	86	10.2	$59,113
MDC 25 (Human Immunodeficiency Virus Infections)--Cases with CRRT	59	15.6	$50,581

As shown in the table, the top five MDCs with the largest number of cases reporting CRRT are MDC 18, with 6,761 cases; MDC 05, with 6,027 cases; MDC 04, with 1,370 cases; MDC 11, with 1,134 cases; and MDC 06, with 987 cases. The top five MDCs with the highest average costs for cases reporting the use of CRRT were MDC 13, with average costs of $131,252; MDC 22, with average costs of $104,749; MDC 17, with average costs of $95,309; MDC 07, with average costs of $87,272; and MDC 05, with average costs of $86,024. The claims data indicate that the average length of stay ranges from a high of 47.3 days in MDC 13 to a low of 8 days in MDC 14 for cases reporting the use of CRRT across each of the 25 MDCs.

We also examined claims from the September 2020 update of the FY 2020 MedPAR file across each of the 25 MDCs to determine the number of cases

reporting the use of CRRT. Our findings are shown in this table.

Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases with CRRT	20,385	16.5	$70,398
MDC 01 (Diseases and Disorders of the Nervous System)--Cases with CRRT	549	17.6	$67,407
MDC 02 (Disease and Disorders of the Eye)--Cases with CRRT	3	15.7	$50,915
MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)--Cases with CRRT	15	19.1	$68,270
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases with CRRT	2,191	18.4	$71,644
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases with CRRT	5,516	17.4	$87,875
MDC 06 (Diseases and Disorders of the Digestive System)--Cases with CRRT	838	17.2	$71,559
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases with CRRT	803	21.1	$86,894
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases with CRRT	357	18.7	$77,515
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases with CRRT	73	13.8	$50,455

Continuous Renal Replacement Therapy Across All MDCs			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)--Cases with CRRT	361	12.5	$39,170
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases with CRRT	1,066	15.9	$54,348
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases with CRRT	12	16.8	$59,223
MDC 13 (Diseases and Disorders of the Female Reproductive System)--Cases with CRRT	18	12.8	$45,623
MDC 14 (Pregnancy, Childbirth and the Puerperium)--Cases with CRRT	1	14	$37,193
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases with CRRT	107	16.4	$63,682
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases with CRRT	209	21.9	$88,182
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases with CRRT	7,678	14.7	$59,317
MDC 19 (Mental Diseases and Disorders)--Cases with CRRT	5	18.4	$36,453
MDC 20 (Alcohol/Drug Use and Alcohol/Drug Induced Organic Mental Disorders)--Cases with CRRT	5	11	$37,345
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases with CRRT	393	14.7	$61,513
MDC 22 (Burns)--Cases with CRRT	41	26.7	$139,224
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)--Cases with CRRT	8	14.1	$40,364
MDC 24 (Multiple Significant Trauma)--Cases with CRRT	78	14.6	$68,916
MDC 25 (Human Immunodeficiency Virus Infections)--Cases with CRRT	58	16.3	$65,767

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As shown in the table, the top five MDCs with the largest number of cases reporting CRRT are MDC 18, with 7,678 cases; MDC 05, with 5,516 cases; MDC

04, with 2,191 cases; MDC 11, with 1,066 cases; and MDC 06, with 838 cases. The top five MDCs with the highest average costs for cases reporting the use of CRRT were MDC 22, with average costs of $139,244; MDC 17, with average costs of $88,182; MDC 05, with average costs of $87,875; MDC 07, with average costs of $86,894; and MDC 08, with average costs of $ 77,515. The claims data indicate that the average length of stay ranges from a high of 26.7 days in MDC 22 to a low of 11 days in MDC 20 for cases reporting the use of CRRT across each of the 25 MDCs.

Our clinical advisors reviewed the clinical issues and the claims data, and did not support creating new MS–DRGs for CRRT without regard to principal diagnosis. Our clinical advisors noted that more than one modality for RRT can be utilized for managing patients with AKI given the needs of the patient. For example, a patient may initially start on CRRT when they are hemodynamically unstable, but transition to IHD as their condition is managed during the admission. While patients requiring CRRT can be more resource intensive, it would not be practical to create new MS–DRGs specifically for this subset of patients given the various clinical presentations for which CRRT may be utilized, and the variation of costs in their assigned MS–DRGs. We believe that additional analysis and efforts toward a broader approach to refining the MS–DRGs for cases of patients requiring renal replacement therapy would be needed to address the concerns expressed by the requestor. These data do show cases reporting the use of CRRT can present greater treatment difficulty. However, when reviewing consumption of hospital resources for this subset of cases, the claims data also suggest that the increased costs may be attributable to the severity of illness of the patient and other circumstances of the admission.

In summary, the claims data reflect a wide variance with regard to the frequency and average costs for cases reporting the use of CRRT. Depending on the number of cases in each MS–DRG, it is difficult to detect patterns of complexity and resource intensity. We believe the creation of new MS–DRGs for cases with procedure codes reporting the use of CRRT has the potential for creating instability in the relative weights and disrupting the integrity of the MS–DRG system. Therefore, we are not proposing to create new MS–DRGs for cases reporting the use of continuous renal replacement therapy.

8. MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders)

a. ANDEXXA® (Coagulation Factor Xa (Recombinant), Inactivated-zhzo)

ANDEXXA® (coagulation factor Xa (recombinant), inactivated-zhzo) is a recombinant decoy protein that rapidly reverses the anticoagulant effects of two direct oral anticoagulants, apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding in indications such as intracranial hemorrhages (ICHs) and gastrointestinal bleeds (GIBs). ANDEXXA® received FDA approval on May 3, 2018. When administered as a bolus followed by continuous infusion, ANDEXXA® blocks the anticoagulants ability to inhibit FXa. ANDEXXA® was approved for new technology add on payments in FY 2019 (83 FR 41362). We refer readers to section II.H.5.j. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41355 through 41362), and section II.H.4.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42193 through 42194) for a complete discussion of the new technology add on payment application and payment amount for ANDEXXA® for FY 2019 and FY 2020.

In section II.H.4.i. of the preamble of the FY 2021 IPPS/LTCH PPS final rule (85 FR 58614 through 58615), we noted the 3-year anniversary date of the entry of ANDEXXA® onto the U.S. market (May 3, 2021) will occur in the second half of FY 2021. We stated in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. After consideration of the public comments received, we finalized our proposal to continue new technology add-on payments for this technology for FY 2021.

We received a request from the manufacturer to review potential access issues in the inpatient setting for this drug in the future. The requestor acknowledged that CMS approved the new technology add-on payment for ANDEXXA® beginning in FY 2019 and noted that FY 2021 will be the last year before the add-on payments expire. According to the requestor, ANDEXXA® is the only indicated factor Xa inhibitor reversal agent, and the requestor stated a concern for the future of access to ANDEXXA® for patients experiencing uncontrolled bleeds caused by factor Xa inhibitors. The requestor stated their claims modeling showed a significant drop in hospital payment for cases involving use of ANDEXXA® following the expiration of new technology add-on payments. Specifically, after new technology add-on payments expire, the requestor stated their model projects that approximately 59% of cases are likely to be paid less than the wholesale acquisition costs for ANDEXXA®.

The following ICD–10–PCS procedure codes identify the intravenous administration of ANDEXXA®.

ICD-10-PCS Code	Code Description
XW03372	Introduction of inactivated coagulation factor Xa into peripheral vein, percutaneous approach, new technology group 2
XW04372	Introduction of inactivated coagulation factor Xa into central vein, percutaneous approach, new technology group 2

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes XW03372 and XW04372 are designated as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors agree that the principal diagnosis assigned for inpatient admissions where the intravenous administration of ANDEXXA® is indicated can vary.

To evaluate the frequency with which the intravenous administration of

ANDEXXA® is reported for different clinical scenarios, we examined claims data from the March 2020 update of the FY 2019 MedPAR file across the Pre-MDC category, each of the 25 MDCs and the surgical class referred to as ''unrelated operating room procedures'' to determine the number of cases reporting the use of ANDEXXA®. Our findings are shown in the following table.

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Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases reporting XW03372 or XW04372	461	8.7	$42,734
Pre-MDC--Cases reporting XW03372 or XW04372	16	19.9	$107,741
MDC 01 (Diseases and Disorders of the Nervous System)--Cases reporting XW03372 or XW04372	250	7.2	$37,035
MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat)--Cases reporting XW03372 or XW04372	2	4	$26,463
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases reporting XW03372 or XW04372	12	5.3	$36,198
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases reporting XW03372 or XW04372	33	16.8	$77,284
MDC 06 (Diseases and Disorders of the Digestive System)--Cases reporting XW03372 or XW04372	53	7.4	$34,485
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases reporting XW03372 or XW04372	2	5	$27,206
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases reporting XW03372 or XW04372	14	7.9	$41,082
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases reporting XW03372 or XW04372	1	4	$22,242
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases reporting XW03372 or XW04372	10	7.5	$32,751

Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases reporting XW03372 or XW04372	1	14	$25,975
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases reporting XW03372 or XW04372	10	7.4	$40,563
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases reporting XW03372 or XW04372	3	11.7	$36,541
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases reporting XW03372 or XW04372	25	11.5	$43,355
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases reporting XW03372 or XW04372	13	6.4	$38,250
MDC 24 (Multiple Significant Trauma)--Cases reporting XW03372 or XW04372	10	10.8	$48,410
MS-DRG 981 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	5	9	$53,775
MS-DRG 987 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	1	12	$31,378

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As shown in the table, there were 461 cases reporting the intravenous administration of ANDEXXA® with procedure codes XW03372 or XW04372. The top five MDCs with the largest number of cases reporting ANDEXXA® are MDC 01, with 250 cases; MDC 06 with 53 cases; MDC 05, with 33 cases; MDC 18, with 25 cases; and the Pre-MDC category, with 16 cases. The claims data indicate that the average costs range from a high of $107,741 in the Pre-MDC category to a low of $22,242 in MDC 09 for cases reporting the use of ANDEXXA® across the claims data. The claims data also indicates that the average length of stay ranges from a high of 19.9 days in the Pre-MDC category to a low of 4 days in MDC 09 for cases reporting the use of ANDEXXA®.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file across the Pre-MDC category, each of the 25 MDCs and the surgical class referred to as ''unrelated operating room procedures'' to determine the number of cases reporting the use of ANDEXXA®. Our findings are shown in the following table.

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Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
All cases reporting XW03372 or XW04372	719	8.3	$44,393
Pre-MDC--Cases reporting XW03372 or XW04372	28	25	$123,750
MDC 01 (Diseases and Disorders of the Nervous System)--Cases reporting XW03372 or XW04372	364	7.1	$38,841
MDC 04 (Diseases and Disorders of the Respiratory System)--Cases reporting XW03372 or XW04372	13	4.5	$35,988
MDC 05 (Diseases and Disorders of the Circulatory System)--Cases reporting XW03372 or XW04372	50	9.4	$58,583
MDC 06 (Diseases and Disorders of the Digestive System)--Cases reporting XW03372 or XW04372	98	7.8	$39,890
MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas)--Cases reporting XW03372 or XW04372	5	9.2	$31,730
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)--Cases reporting XW03372 or XW04372	15	7.4	$45,397
MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast)--Cases reporting XW03372 or XW04372	9	4.8	$27,922
MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders)--Cases reporting XW03372 or XW04372	1	8	$33,210

Cases Reporting ANDEXXA® Therapy			
MDC	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)--Cases reporting XW03372 or XW04372	9	8.7	$36,565
MDC 12 (Diseases and Disorders of the Male Reproductive System)--Cases reporting XW03372 or XW04372	1	8	$30,119
MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders)--Cases reporting XW03372 or XW04372	22	5.7	$28,458
MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms)--Cases reporting XW03372 or XW04372	1	5	$34,819
MDC 18 (Infectious and Parasitic Diseases, Systemic or Unspecified Sites)--Cases reporting XW03372 or XW04372	52	9.7	$50,963
MDC 19 (Mental Diseases and Disorders)--Cases reporting XW03372 or XW04372	1	15	$37,667
MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs)--Cases reporting XW03372 or XW04372	9	4.2	$27,987
MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services)--Cases reporting XW03372 or XW04372	1	7	$28,405
MDC 24 (Multiple Significant Trauma)--Cases reporting XW03372 or XW04372	30	8.4	$41,478
MS-DRG 981 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	9	11.6	$57,895
MS-DRG 987 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) --Cases reporting XW03372 or XW04372	1	5	$34,910

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As shown in the table, there were 719 cases reporting the intravenous administration of ANDEXXA® with procedure codes XW03372 or XW04372. The top five MDCs with the largest number of cases reporting ANDEXXA® are MDC 01, with 364 cases; MDC 06 with 98 cases; MDC 18, with 52 cases; MDC 05, with 50 cases; and MDC 24, with 30 cases. The claims data indicate that the average costs range from a high

of $123,750 in the Pre-MDC category to a low of $27,922 in MDC 09 for cases reporting the use of ANDEXXA® across the claims data. The claims data also indicates that the average length of stay ranges from a high of 25 days in the Pre-MDC category to a low of 4.2 days in MDC 21 for cases reporting the use of ANDEXXA® across the claims data.

To further examine the impact of the intravenous administration of ANDEXXA®, we examined claims data from the March 2020 update of the FY 2019 MedPAR file for the top ten MS–DRGs reporting procedure codes XW03372 or XW04372. Our findings are reflected in the following table:

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Top 10 MS-DRGs Reporting ANDEXXA® Therapy

MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
064	Intracranial Hemorrhage or Cerebral Infarction with MCC	All cases	77,911	6.1	$13,441
		Cases reporting XW03372 or XW04372	78	6.9	$30,187
023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator	All cases	12,867	9.8	$40,511
		Cases reporting XW03372 or XW04372	27	11	$53,956
086	Traumatic Stupor and Coma <1 Hour with CC	All cases	16,035	3.9	$9,214
		Cases reporting XW03372 or XW04372	25	4.2	$28,603
377	Gastrointestinal Hemorrhage with MCC	All cases	68,798	5.7	$12,897
		Cases reporting XW03372 or XW04372	18	8.6	$35,850
025	Craniotomy and Endovascular Intracranial Procedures with MCC	All cases	21,980	8.8	$31,726
		Cases reporting XW03372 or XW04372	17	9	$55,458
083		All cases	10,061	4.3	$9,895

Top 10 MS-DRGs Reporting ANDEXXA® Therapy					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
	Traumatic Stupor and Coma >1 Hour with CC	Cases reporting XW03372 or XW04372	17	4.4	$26,992
082	Traumatic Stupor and Coma >1 Hour with MCC	All cases	6,980	6.4	$16,630
		Cases reporting XW03372 or XW04372	15	7.6	$30,208
085	Traumatic Stupor and Coma <1 Hour with MCC	All cases	8,178	6.5	$16,116
		Cases reporting XW03372 or XW04372	15	6.7	$32,475
065	Intracranial Hemorrhage or Cerebral Infarction with CC or TPA In 24 Hours	All cases	107,737	3.6	$7,375
		Cases reporting XW03372 or XW04372	14	5	$26,992
003	ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face Mouth and Neck with Major O.R. Procedures	All cases	14,532	30.2	$128,196
		Cases reporting XW03372 or XW04372	13	21.5	$117,265

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As shown in this table, the claims data demonstrate that the MS–DRG with the largest number of cases reporting ANDEXXA® is MS–DRG 064 with 78 cases. Of the top 10 MS–DRGs reporting ANDEXXA®, the MS–DRG with the smallest number of cases is MS–DRG 003 with 13 cases. The average length of stay of this subset of cases ranges from a high of 21.5 days in MS–DRG 003 to a low of 4.2 days in MS–DRG 086 for cases reporting the use of ANDEXXA®. The average costs of this subset of cases ranges from a high of $117,265 in MS–DRG 003 to a low of $26,992 in MS–DRG 083 for cases reporting the use of ANDEXXA®. We note while our data findings demonstrate the average costs were higher for the cases reporting the intravenous administration of ANDEXXA® when compared to all cases in their respective MS–DRG, these cases represent a very small percentage of the total number of cases reported in these MS–DRGs. We also note that the top 10 MS–DRGs identified only account for 239 of the 461 cases in total that were identified in the March 2020 update of the FY 2019 MedPAR file reporting ICD–10–PCS codes XW03372 or XW04372. The remainder of the cases are distributed in small numbers across the MS–DRGs.

We also examined claims data from the September 2020 update of the FY 2020 MedPAR file for the top ten MS–DRGs reporting procedure codes XW03372 or XW04372. Our findings are reflected in the following table:

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Top 10 MS-DRGs Reporting ANDEXXA® Therapy					
MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
025	Craniotomy and Endovascular Intracranial Procedures with MCC	All cases	19,643	8.7	$32,933
		Cases reporting XW03372 or XW04372	25	9.3	$59,478
023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator	All cases	12,042	9.7	$42,273
		Cases reporting XW03372 or XW04372	38	10	$58,749
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	552,641	6.4	$14,140
		Cases reporting XW03372 or XW04372	26	9	$46,965
377	Gastrointestinal Hemorrhage with MCC	All cases	60,818	5.6	$13,369
		Cases reporting XW03372 or XW04372	36	6.0	$37,949
085	Traumatic Stupor and Coma <1 Hour with MCC	All cases	7,402	6.4	$16,512
		Cases reporting XW03372 or XW04372	29	8.4	$36,530
064	Intracranial Hemorrhage or Cerebral Infarction with MCC	All cases	68,674	6	$13,997
		Cases reporting XW03372 or XW04372	111	6.8	$34,892
083	Traumatic Stupor and Coma >1 Hour with CC	All cases	9,036	4.2	$10,419
		Cases reporting XW03372 or XW04372	23	4.7	$32,678
065	Intracranial Hemorrhage or Cerebral Infarction with CC or TPA In 24 Hours	All cases	86,862	3.5	$7,583
		Cases reporting XW03372 or XW04372	32	5.2	$31,535
086	Traumatic Stupor and Coma <1 Hour with CC	All cases	13,298	3.7	$9,592
		Cases reporting XW03372 or XW04372	41	4.4	$29,221
378	Gastrointestinal Hemorrhage with CC	All cases	101,534	3.5	$7,577
		Cases reporting XW03372 or XW04372	24	3.5	$24,348

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As shown in this table, the claims data demonstrate that the MS–DRG with the largest number of cases reporting ANDEXXA® is MS–DRG 064 with 111 cases. Of the top 10 MS–DRGs reporting ANDEXXA®, the MS–DRG with the smallest number of cases is MS–DRG 083 with 23 cases. The average length of stay of this subset of cases ranges from a high of 10 days in MS–DRG 023 to a low of 3.5 days in MS–DRG 378 for cases reporting the use of ANDEXXA®. The average costs of this subset of cases ranges from a high of $59,478 in MS–DRG 025 to a low of $24,348 in MS–DRG 378 for cases reporting the use of ANDEXXA®. As with our analysis of the

FY 2019 claims data, while these data findings demonstrate the average costs were higher for the cases reporting the intravenous administration of ANDEXXA® when compared to all cases in their respective MS–DRG, these cases represent a very small percentage of the total number of cases reported in these MS–DRGs. We also note that the top 10 MS–DRGs identified only account for 385 of the 719 cases in total that were identified in the September 2020 update of the FY 2020 MedPAR file reporting ICD–10–PCS codes XW03372 or XW04372. The remainder of the cases are distributed in small numbers across the MS–DRGs.

After reviewing the claims data, we believe it is premature to consider a proposal for cases involving ANDEXXA® therapy for FY 2022. While the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file do contain claims reporting the procedure codes identifying the intravenous administration of ANDEXXA®, the number of cases is small across the MDCs and MS–DRGs. The claims data also reflect a wide variance with regard to the frequency and average costs for these cases reporting the use of ANDEXXA®. Moreover, we were unable to identify another MS–DRG that would be a more appropriate MS–DRG assignment for these cases based on the indication for this therapeutic drug. As noted previously, ANDEXXA® reverses the anticoagulant effects of apixaban and rivaroxaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. The underlying cause of the life-threatening or uncontrolled bleeding can vary which means the principal diagnosis assigned for inpatient admissions where ANDEXXA® is administered can vary. The MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets based on the drugs administered. In reviewing this issue, our clinical advisors expressed concern regarding making potential MS–DRG changes based on a specific, single therapeutic agent, identified by unique procedure codes rather than based on a group of related procedure codes that can be reported to describe that same type or class of treatment or technology, which is more consistent with the intent of the MS–DRGs.

We recognize the average costs of the small numbers of cases involving the intravenous administration of ANDEXXA® are greater when compared to the average costs of all cases in their respective MS–DRG. The MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We further note that section 1886(d)(5)(A) of the Act provides for Medicare payments to Medicare-participating hospitals in addition to the basic prospective payments for cases incurring extraordinarily high costs.

We acknowledge the importance of ensuring that patients diagnosed with an indication for a factor Xa inhibitor reversal agent have adequate access to care and receive the necessary treatment. While we are sensitive to the requestors' concerns about continued access to treatment for beneficiaries who require the reversal of anticoagulation due to life-threatening or uncontrolled bleeding, additional time is needed to explore options and other mechanisms through which to address low volume high-cost drugs outside of the MS–DRGs.

Furthermore, we note that we are proposing to continue new technology add-on payments for ANDEXXA® for FY 2022. We refer the reader to section II.F.4.b of the preamble of this proposed rule for further discussion regarding our proposal to allow a one-time extension of new technology add-on payments for FY 2022 for 15 technologies for which the new technology add-on payment would otherwise be discontinued, in connection with our proposal to use the FY 2019 data to develop the proposed FY 2022 relative weights.

Therefore for the reasons stated previously, for FY 2022 we are not proposing any MS–DRG changes for cases involving the intravenous administration of ANDEXXA®.

b. Cytokine Release Syndrome (CRS) Logic

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58557 through 58561), we finalized modifications to the proposed severity level designations for a subset of the diagnosis codes describing Cytokine Release Syndrome (CRS) based upon further review of the conditions and in response to public comments. We provided the following table to display the finalized severity level designations and stated that we will continue to monitor the CRS codes and their impact on resource use once the claims data becomes available to determine if further modifications to the severity level are warranted.

ICD-10-CM Code	Description	Proposed Severity Level	Finalized Severity Level
D89.83l	Cytokine release syndrome, grade 1	NonCC	NonCC
D89.832	Cytokine release syndrome, grade 2	NonCC	NonCC
D89.833	Cytokine release syndrome, grade 3	NonCC	CC
D89.834	Cytokine release syndrome, grade 4	NonCC	CC
D89.835	Cytokine release syndrome, grade 5	NonCC	CC
D89.839	Cytokine release syndrome, grade unspecified	NonCC	NonCC

In connection with the finalized severity level designations for the listed CRS codes, we also finalized modifications to the ICD–10 MS–DRG GROUPER logic V38 for MS–DRGs 814, 815, and 816 (Reticuloendothelial and Immunity Disorders with MCC, with CC, and without CC/MCC, respectively) to conform to the updates the CDC finalized in the ICD–10–CM Tabular List instructions for assigning and reporting the CRS codes effective with discharges on and after October 1, 2020. The following modifications to the GROUPER logic were finalized effective with discharges on and after October 1, 2020, for case assignment involving CRS following CAR T-cell therapy to MS–

DRGs 814, 815, and 816. We noted that the GROUPER logic for MS–DRGs 814, 815, and 816 will include a principal diagnosis of T89.89XA with a secondary diagnosis of any CRS code as shown in this section of this proposed rule.

Principal Diagnosis

T80.89XA Other complications following infusion, transfusion and therapeutic injection, initial encounter

with

Secondary Diagnosis

D89.831 Cytokine release syndrome, grade 1
D89.832 Cytokine release syndrome, grade 2
D89.833 Cytokine release syndrome, grade 3
D89.834 Cytokine release syndrome, grade 4
D89.835 Cytokine release syndrome, grade 5
D89.839 Cytokine release syndrome, grade unspecified

As discussed in section II.D.13 of the preamble of this proposed rule, Table 6A.-New Diagnosis Codes, lists the new diagnosis codes that have been approved to date and will be effective with discharges on and after October 1, 2021. Included in Table 6A are the following codes that describe complication of immune effector cellular therapy identifying the timeframe of the encounter.

ICD-10-CM Code	Description
T80.82XA	Complication of immune effector cellular therapy, initial encounter
T80.82XD	Complication of immune effector cellular therapy, subsequent encounter
T80.82XS	Complication of immune effector cellular therapy, sequela

Also included in Table 6A are the following diagnosis codes that describe immune effector cell-associated neurotoxicity syndrome (ICANS), with varying degrees of severity.

ICD-10-CM Code	Description
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5

Consistent with the Tabular List instruction for these two sets of diagnosis codes as presented and discussed by the CDC at the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting, the diagnosis codes describing a complication of the immune effector cellular therapy (T80.82XA, T80.82XD, and T80.82XS) are to be sequenced first, followed by the applicable diagnosis code to identify the specified condition resulting from the complication. For example, the types of complications that may result from immune effector cellular therapy treatment (for example, CAR T-cell therapy) include ICANS or CRS, as described by the listed diagnosis codes. Accordingly, the CDC included the following instructional note in the Tabular List modifications for code T80.82–

''Use additional code to identify the specific complication, such as: cytokine release syndrome (D89.83–) immune effector cell-associated neurotoxicity syndrome (G92.0–)''

Materials relating to the discussions involving the diagnosis codes from the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting can be obtained from the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm*.

As noted previously, the current logic for case assignment involving CRS following CAR T-cell therapy to MS–DRGs 814, 815, and 816 includes a principal diagnosis of T89.89XA with a secondary diagnosis of any CRS code. However, with the finalization of new diagnosis code T80.82-, diagnosis code T89.89XA would no longer be reported and these cases would instead report new diagnosis code T80.82XA, effective with discharges on and after October 1, 2020. As shown in Table 6A associated with this proposed rule, we are proposing to assign diagnosis code T80.82XA to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, and Immunologic Disorders) in MS–DRGs 814, 815, and 816. If the MDC and MS–DRG assignment for new diagnosis code T80.82XA is finalized, the current logic for MS–DRGs 814, 815, and 816 that includes a principal diagnosis code of T89.89XA with a secondary diagnosis code of any CRS code would no longer be appropriate or necessary.

Therefore, we are proposing to revise the structure of MS–DRGs 814, 815, and 816 by removing the logic that includes a principal diagnosis of T89.89XA with a secondary diagnosis of any CRS code from MS–DRGs 814, 815, and 816 effective FY 2022.

9. MDC 17 (Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms): Inferior Vena Cava Filter Procedures

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58517 through 58520), we

discussed the ICD–10–PCS codes that describe the insertion of an intraluminal device into the inferior vena cava that are listed in the following table.

ICD-10-PCS Code	Code Description
06H003T	Insertion of infusion device, via umbilical vein, into inferior vena cava, open approach
06H003Z	Insertion of infusion device, into inferior vena cava, open approach
06H00DZ	Insertion of intraluminal device, into inferior vena cava, open approach
06H033T	Insertion of infusion device, via umbilical vein, into inferior vena cava, percutaneous approach
06H033Z	Insertion of infusion device, into inferior vena cava, percutaneous approach
06H03DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous approach
06H043Z	Insertion of infusion device, into inferior vena cava, percutaneous endoscopic approach
06H04DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous endoscopic approach

We finalized a change in the designation of ICD–10–PCS procedure code 06H03DZ from O.R. procedure to non-O.R. procedure and maintained the O.R. designation of procedure codes 06H00DZ and 06H04DZ. In that discussion, we noted our clinical advisors supported changing the O.R. designation of procedures describing insertion of an intraluminal device into the inferior vena cava performed via a percutaneous approach since the procedure does not require the resources of an operating room, while concurring that procedures describing the insertion of an intraluminal device into the inferior vena cava performed via an open or a percutaneous endoscopic approach could require greater resources than a procedure describing insertion of an intraluminal device into the inferior vena cava performed via a percutaneous approach. We also noted that the goals of changing the designation of procedures from non-O.R. to O.R., or vice versa, are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system and not whether the change in designation would impact payment in a particular direction.

In response to this final policy, for this FY 2022 IPPS/LTCH PPS proposed rule, we received a request to revise MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with and without CC/MCC, respectively) by removing the current two-way severity level split and creating a three-way severity level split. The requestor respectfully disagreed with the FY 2021 IPPS/LTCH PPS final rule decision to change the designation of the procedure code describing the insertion of an inferior vena cava intraluminal device via percutaneous approach to a non-O.R. procedure, and stated vena cava filters are most often placed in interventional radiology suites and require a high level of skill to prevent rupture of the vena cava; and although they are long-term devices, they must be placed skillfully to allow for removal later if needed.

According to the requestor, it is a conundrum that patients with principal and secondary diagnoses that qualify for medical MS–DRGs 837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC), MS–DRG 838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent), and MS–DRG 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC) group to lower weighted surgical MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with and without CC/MCC, respectively) when a non-major O.R. procedure is performed. The requestor stated the difference in relative weights might be occurring because of the two-way split within MS–DRGs 829 and 830 and the three-way split within MS–DRGs 837, 838 and 839. The requestor theorized that removing the current two-way severity level split of MS–DRGs 829 and 830 and creating a three-way severity level split could help resolve the relative weight discrepancy when any non-major O.R. procedures are performed during hospitalizations for chemotherapy for acute leukemia.

This requestor also suggested that if CMS' analysis did not support creating a three-way split for MS–DRGs 829 and 830, exclusion of PCS code 06H03DZ from the list of qualifying procedures and reinstatement of O.R. procedure status to appropriately compensate providers for the cost of devices and resources to place inferior vena cava filters across the patient population should be proposed.

To evaluate the request to create a three-way severity split MS–DRG for cases reporting myeloproliferative disorders or poorly differentiated neoplasms with other procedures, we conducted an analysis of base MS–DRG 829. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported.

Therefore, we reviewed the claims data for base MS–DRG 829 using the September 2018 update of the FY 2018 MedPAR file and the March 2020 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2022, respectively. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	2,099	686	1,080	333	$21,657	$35,618	$16,103	$10,909	$23,684	$14,879
2018	2,116	668	1,115	333	$20,355	$33,693	$15,513	$9,811	$22,324	$14,202

We applied the criteria to create subgroups for the three-way severity level split. We found that the criterion that there be at least 500 cases for each subgroup was not met based on the data in both the FY 2018 and FY 2019 MedPAR files, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 333 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2019 MedPAR file and only 333 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2018 MedPAR file. Accordingly, the claims data do not support a three-way severity level split for base MS–DRG 829.

We also reviewed the claims data for base MS–DRG 829 using the September 2019 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2021 and FY 2022, respectively. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases NonCC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs NonCC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2020	1,993	647	1,043	303	$20,494	$31,734	$16,220	$11,204	$22,159	$15,091
2019	2,099	686	1,080	333	$21,657	$35,618	$16,103	$10,909	$23,684	$14,879

We applied the criteria to create subgroups for the three-way severity level split. We found that the criterion that there be at least 500 cases for each subgroup was not met based on the data in both the FY 2019 and FY 2020 MedPAR files, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 303 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2020 MedPAR file and, as previously noted, only 333 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2019 MedPAR file. As shown in both sets of data and stated previously, the claims data do not support a three-way severity level split for base MS–DRG 829.

In response to the request to exclude ICD–10–PCS code 06H03DZ from a list of qualifying procedures if CMS's analysis did not support creating a three-way split for MS–DRGs 829 and 830, by definition, procedure codes designated as non-O.R. procedures, not further classified as ''affecting the MS–DRG assignment'', do not influence the MS–DRG assignment. As stated previously, in the FY 2021 IPPS/LTCH PPS final rule we finalized our proposal to change the designation of ICD–10–PCS procedure code 06H03DZ from O.R. procedure to non-O.R. procedure, therefore as a non-O.R. procedure, there is no need to exclude ICD–10–PCS code 06H03DZ from a list of qualifying procedure codes for MS–DRGs 829 and 830.

In response to the request to reinstate the O.R. procedure designation of ICD–10–PCS code 06H03DZ if CMS's analysis did not support creating a three-way split for MS–DRGs 829 and 830, the change in designation from O.R. procedure to non-O.R. procedure is recent, only becoming effective October 1, 2020. Our clinical advisors continue to indicate that code 06H03DZ, describing the percutaneous insertion of an intraluminal device into the inferior vena cava, does not require the resources of an operating room, that the procedure to insert an IVC filter percutaneously is not surgical in nature and that the resources involved in furnishing this procedure are comparable to the related ICD–10–PCS procedure codes that describe the insertion of infusion devices into the inferior vena cava that are currently designated as non-O.R. procedures. Our clinical advisors state our FY 2021 final policy results in an O.R. designation of 06H03DZ that better reflects the associated technical complexity and hospital resource use of this procedure. We continue to explore alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data, as discussed in the FY 2021 IPPS/LTCH PPS final rule and in section II.D.11. of the preamble of this proposed rule. We continue to develop our process and methodology, and will provide more detail in future rulemaking.

In summary, based on the results of our analysis, for FY 2022, we are proposing to maintain the current structure of MS–DRGs 829 and 830.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS DRGs to which the procedure codes are assigned.

Based on the results of our review of the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we are proposing to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

As discussed in section II.D.3.b. of the preamble of this proposed rule, we received a request to reassign cases with procedures describing control of bleeding in the cranial cavity when reported with a central nervous system diagnosis from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MDC 01 (Diseases and Disorders of the Central Nervous System) in MS–DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively (for example, ''craniotomy'' MS–DRGs). We note that in addition to MS–DRGs 25, 26, and 27, MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) also include procedures performed on structures located within the cranial cavity and are included in the range of MS–DRGs known as the ''craniotomy'' MS–DRGs in MDC 01.

The management and treatment for bleeding (or hemorrhage) within the cranial cavity varies depending on the location, cause and the severity (or extent) of the bleed. Common causes include head trauma or cerebral aneurysm. Control of bleeding in the cranial cavity procedures are identified by ICD–10–PCS procedure codes 0W310ZZ (Control bleeding in cranial cavity, open approach), 0W313ZZ (Control bleeding in cranial cavity, percutaneous approach) and 0W314ZZ (Control bleeding in cranial cavity, percutaneous endoscopic approach) and are currently assigned to the following MDCs and MS–DRGs.

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MDC	Description	MS-DRG	Description
03	Diseases and Disorders of the Ear, Nose, Mouth and Throat	143	Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC
		144	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC
		145	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC
05	Diseases and Disorders of the Circulatory System	264	Other Circulatory System O.R. Procedures
10	Endocrine, Nutritional and Metabolic Diseases and Disorders	628	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC
		629	Other Endocrine, Nutritional and Metabolic O.R. Procedures with CC
		630	Other Endocrine, Nutritional and Metabolic O.R. Procedures without CC/MCC
17	Myeloproliferative Diseases and Disorders, and Poorly Differentiated Neoplasms	820	Lymphoma and Leukemia with Major O.R. Procedures with MCC
		821	Lymphoma and Leukemia with Major O.R. Procedures with CC
		822	Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC
		826	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC
		827	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with CC
		828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures without CC/MCC
21	Injuries, Poisonings and Toxic Effects of Drugs	907	Other O.R. Procedures for Injuries with MCC
		908	Other O.R. Procedures for Injuries with CC
		909	Other O.R. Procedures for Injuries without CC/MCC
24	Multiple Significant Trauma	957	Other O.R. Procedures for Multiple Significant Trauma with MCC
		958	Other O.R. Procedures for Multiple Significant Trauma with CC
		959	Other O.R. Procedures for Multiple Significant Trauma without CC/MCC

BILLING CODE 4120–01–C

According to the requestor, procedures performed within the cranial cavity always involve drilling or cutting through the skull regardless of the

approach, therefore the three procedure codes identified (0W310ZZ, 0W313ZZ, and 0W314ZZ) warrant assignment to the ''craniotomy'' MS–DRGs.

Our analysis of this grouping issue confirmed that when a procedure describing control of bleeding in the cranial cavity is reported with a principal diagnosis from MDC 01, these cases group to MS–DRGs 981, 982, and 983. Whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting any one of the three procedure codes (0W310ZZ, 0W313ZZ or 0W314ZZ) in MS–DRGs 981 through 983 with a principal diagnosis from MDC 01. Our findings are shown in the following tables.

MS-DRGs 981-983: Cases Reporting Procedures Describing Control of Bleeding in Cranial Cavity with a Principal Diagnosis from MDC 01 – FY 2019

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981 -	All cases	26,451	11.7	$32,022
981 -	Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	8	9.8	$30,843
982 -	All cases	13,853	6.2	$18,176
982 -	Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	9.0	$51,234
983-	All cases	2,652	3.0	$12,163
983 -	Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	4.0	$14,934

MS-DRGs 981-983: Cases Reporting Procedures Describing Control of Bleeding in Cranial Cavity with a Principal Diagnosis from MDC 01 – FY 2020

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
981 -	All cases	22,819	11.5	$33,620
981 -	Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	18.0	$38,565
982 -	All cases	11,052	6.0	$18,608
983 -	All cases	2,003	2.7	$13,396
983 -	Cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01	1	4.0	$9,152

As noted previously, the requestor asked that we consider reassignment of these cases to the craniotomy MS–DRGs (identified as MS–DRGs 23, 24, 25, 26, and 27). We therefore examined the data for all cases in MS–DRGs 23, 24, 25, 26, and 27. Our findings are shown in the following tables.

MS-DRGs 23 through 27: All Cases – FY 2019			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
23 - All cases	12,867	9.8	$40,511
24 - All cases	4,624	5.2	$28,583
25 - All cases	21,980	8.8	$31,726
26 - All cases	9,547	5.3	$22,347
27 - All cases	10,495	2.5	$18,574

MS-DRGs 23 through 27: All Cases – FY 2020			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
23 - All cases	12,042	9.7	$42,273
24 - All cases	4,087	5.1	$30,278
25 - All cases	19,643	8.7	$32,933
26 - All cases	7,609	5.2	$23,226
27 - All cases	7,866	2.4	$19,427

As shown, in our analyses of the claims data for MS–DRGs 981 through 983, we found a total of ten cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01 in the March 2020 update of the FY 2019 MedPAR file, and a total of two cases reporting procedures describing control of bleeding in cranial cavity with a principal diagnosis from MDC 01 in the September 2020 update of the FY 2020 MedPAR file.

Our clinical advisors stated these procedures describing control of bleeding in the cranial cavity are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 25, 26, and 27, in addition to MS–DRG 23 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS–DRG 24 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) that also describe procedures performed on structures located within the cranial cavity and are included in the range of MS–DRGs known as the ''craniotomy'' MS–DRGs. While the claims analysis based on the March 2020 update of the FY 2019 MedPAR file identified only ten cases and the September 2020 update of the FY 2020 MedPAR file identified only two cases for which these procedures were reported as a stand-alone procedure resulting in assignment to MS–DRGs 981 through 983, and the average length of stay and average costs for these cases vary in comparison to the average length of stay and average costs of all cases in MS–DRGs 23, 24, 25, 26, and 27, given the nature of head trauma cases, the resource use would be expected to vary based on the extent of the patient's injuries. We believe it is clinically appropriate to add these procedure codes describing control of bleeding in the cranial cavity to MS–DRGs 23, 24, 25, 26, and 27 in MDC 01.

Therefore, we are proposing to add procedure codes 0W310ZZ, 0W313ZZ, and 0W314ZZ to MDC 01 in MS–DRGs 23, 24, 25, 26, and 27 (''craniotomy'' MS–DRGs) for FY 2022.

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other.

Based on the results of our review of the claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we are proposing to move the cases reporting the procedures codes described in this section of this rule from MS–DRGs 981 through 983 to MS–DRGs 987 through 989.

As discussed in section II.D.3.a. of the preamble of this proposed rule, we received a request that we understood to be for our consideration of the reassignment of the following three procedure codes from Extensive O.R. procedures to Non-extensive O.R. procedures.

ICD-10-PCS Code	Description
0JB60ZZ	Excision of chest subcutaneous tissue and fascia, open approach
0JB70ZZ	Excision of back subcutaneous tissue and fascia, open approach
0JB80ZZ	Excision of abdomen subcutaneous tissue and fascia, open approach

In conducting our review of this request, our clinical advisors noted that ICD–10–PCS codes 0JB60ZZ, 0JB70ZZ, and 0JB80ZZ currently group to MS–DRGs 981 through 983 when reported with a principal diagnosis that is not assigned to one of the MDCs to which these procedure codes are assigned. While our claims analysis of both the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file did not identify any cases reporting any one of the three listed procedure codes in MS–DRGs 981, 982, or 983, our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list. They stated that these procedures do not consume the resources or require a similar level of technical complexity as the procedures on the Extensive O.R. procedures list.

Therefore, we are proposing to reassign the three procedure codes listed from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) for FY 2022.

As discussed in section II.D.4.b. of the preamble of this proposed rule, we identified 17 procedure codes describing laser interstitial thermal therapy (LITT) that are currently designated as extensive O.R. procedures. In addition to those 17 procedure codes, we identified additional procedure codes describing LITT of various body parts that are also designated as extensive O.R. procedures. The ICD–10–PCS codes describing LITT of various body parts are as follows.

ICD-10-PCS Code	Description
D0Y0KZZ	Laser interstitial thermal therapy of brain
D0Y1KZZ	Laser interstitial thermal therapy of brain stem
D0Y6KZZ	Laser interstitial thermal therapy of spinal cord
D0Y7KZZ	Laser interstitial thermal therapy of peripheral nerve
DBY0KZZ	Laser interstitial thermal therapy of trachea
DBY1KZZ	Laser interstitial thermal therapy of bronchus
DBY2KZZ	Laser interstitial thermal therapy of lung
DBY5KZZ	Laser interstitial thermal therapy of pleura
DBY6KZZ	Laser interstitial thermal therapy of mediastinum
DBY7KZZ	Laser interstitial thermal therapy of chest wall
DBY8KZZ	Laser interstitial thermal therapy of diaphragm
DDY0KZZ	Laser interstitial thermal therapy of esophagus
DDY1KZZ	Laser interstitial thermal therapy of stomach
DDY2KZZ	Laser interstitial thermal therapy of duodenum
DDY3KZZ	Laser interstitial thermal therapy of jejunum
DDY4KZZ	Laser interstitial thermal therapy of ileum
DDY5KZZ	Laser interstitial thermal therapy of colon
DDY7KZZ	Laser interstitial thermal therapy of rectum
DDY8KZZ	Laser interstitial thermal therapy of anus
DFY0KZZ	Laser interstitial thermal therapy of liver
DFY1KZZ	Laser interstitial thermal therapy of gallbladder
DFY2KZZ	Laser interstitial thermal therapy of bile ducts
DFY3KZZ	Laser interstitial thermal therapy of pancreas
DGY0KZZ	Laser interstitial thermal therapy of pituitary gland
DGY1KZZ	Laser interstitial thermal therapy of pineal body
DGY2KZZ	Laser interstitial thermal therapy of adrenal glands
DGY4KZZ	Laser interstitial thermal therapy of parathyroid glands
DGY5KZZ	Laser interstitial thermal therapy of thyroid
DMY0KZZ	Laser interstitial thermal therapy of left breast
DMY1KZZ	Laser interstitial thermal therapy of right breast
DVY0KZZ	Laser interstitial thermal therapy of prostate

Whenever one of these listed procedure codes is reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it currently results in assignment to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Our clinical advisors stated that all of the listed procedure codes warrant redesignation from the extensive procedure list and MS–DRGs 981, 982, and 983 to the non-extensive procedure list and to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Specifically, our clinical advisors stated the procedures described by these codes are minimally invasive and are consistent with other ablation (root operation Destruction) type procedures that are designated as non-extensive procedures in the ICD–10–PCS classification.

In our analysis of claims from the March 2020 update of the FY 2019 MedPAR file, we identified a total of six cases reporting procedure codes describing LITT of various body sites in MS–DRGs 981, 982, and 983 with an average length of stay of 2.5 days and average costs of $7,734. Specifically, we found one case reporting procedure code DVY0KZZ (Laser interstitial thermal therapy of prostate) in MS–DRG 981 with an average length of stay of 4.0 days and average costs of $7,348. For MS–DRG 982, we found five cases in which procedure codes describing LITT of various body sites were reported. The first case reported procedure code D0Y0KZZ (Laser interstitial thermal therapy of brain) with an average length of stay of 1.0 day and average costs of $4,142, the second case reported procedure code D0Y6KZZ (Laser interstitial thermal therapy of spinal cord) with an average length of stay of 3.0 days and average costs of $20,007, the third case reported procedure code DDY1KZZ (Laser interstitial thermal therapy of stomach) with an average length of stay of 2.0 days and average costs of $3,424, the fourth case reported procedure code DDY7KZZ (Laser interstitial thermal therapy of rectum) with an average length of stay of 3.0 days and average costs of $3,735, and

the fifth case reported procedure code DVY0KZZ (Laser interstitial thermal therapy of prostate) with an average length of stay of 2.0 days and average costs of $7,750. There were no cases found to report procedures describing LITT in MS–DRG 983. Our findings are summarized in the following table.

MS-DRGs 981-983: Cases Reporting Procedures Describing LITT – FY 2019

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981 - All cases	26,451	11.7	$32,022
981 - Cases reporting procedures describing LITT	1	4.0	$7,348
982 - All cases	13,853	6.2	$18,176
982 - Cases reporting procedures describing LITT	5	2.2	$7,812
983- All cases	2,652	3.0	$12,163
Total	6	2.5	$7,734

In our analysis of claims from the September 2020 update of the FY 2020 MedPAR file, we identified one case reporting procedure code D0Y6KZZ (Laser interstitial thermal therapy of spinal cord) with an average length of stay of 6 days and average costs of $5,130, and two cases reporting procedure code DVY0KZZ (Laser interstitial thermal therapy of prostate) with an average length of stay of 8.5 days and average costs of $20,329 in MS–DRGs 981, 982, or 983. Although our claims analysis identified a limited number of cases reporting procedures describing LITT, our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list.

Therefore, we are proposing to reassign the listed procedure codes describing LITT of various body parts from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

As also discussed in section II.D.4.b. of the preamble of this proposed rule, we identified five procedure codes describing repair of the esophagus that are currently designated as extensive O.R. procedures. The procedure codes are 0DQ50ZZ (Repair esophagus, open approach), 0DQ53ZZ (Repair esophagus, percutaneous approach), 0DQ54ZZ (Repair esophagus, percutaneous endoscopic approach), 0DQ57ZZ (Repair esophagus, via natural or artificial opening), and 0DQ58ZZ (Repair esophagus, via natural or artificial opening endoscopic). Whenever one of these five procedure codes is reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it currently results in assignment to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Our clinical advisors stated that three of these five procedures warrant redesignation from the extensive procedure list and MS–DRGs 981, 982, and 983 to the non-extensive procedure list and to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Specifically, our clinical advisors stated the procedures identified by procedure codes 0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ do not involve the same utilization of resources with respect to the performance of the procedure in comparison to the procedures identified by procedure codes 0DQ50ZZ and 0DQ540ZZ. In our analysis of claims from the March 2020 update of the FY 2019 MedPAR file, we identified three cases reporting procedure code 0DQ58ZZ in MS–DRGs 981, 982, and 983 with an average length of stay of 14 days and average costs of $34,894. In our analysis of claims from the September 2020 update of the FY 2020 MedPAR file, we identified two cases reporting procedure code 0DQ58ZZ in MS–DRGs 981, 982, or 983 with an average length of stay of 8 days and average costs of $12,037. Our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list. Therefore, we are proposing to reassign these three procedure codes (0DQ53ZZ, 0DQ57ZZ, and 0DQ58ZZ) from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

As discussed in section II.D.11.c.24. of the preamble of this proposed rule, we identified procedure code 0T9D0ZZ (Drainage of urethra, open approach) during our review of procedure code 0U9L0ZZ (Drainage of vestibular gland, open approach), which is currently designated as a non-O.R. procedure. We noted that the procedure described by procedure code 0T9D0ZZ represents the male equivalent of the female procedure described by procedure code 0U9L0ZZ. Procedure code 0T9D0ZZ is currently designated as an extensive O.R. procedure and is reported to describe procedures performed on the Cowper's (bulbourethral) gland in males. Whenever this procedure code is reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it currently results in assignment to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal

Diagnosis with MCC, with CC, without CC/MCC, respectively).

Our clinical advisors stated that this procedure warrants redesignation from the extensive procedure list and MS–DRGs 981, 982, and 983 to the non-extensive procedure list and to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). Specifically, our clinical advisors stated that the procedure described by procedure code 0T9D0ZZ continues to warrant an O.R. designation because it is performed on deeper structures and requires a higher level of technical skill and it is a more complex procedure when compared to the non-O.R. procedure described by procedure code 0U9L0ZZ, however, abscess formation in the Cowper's (bulbourethral) glands is uncommon and can often be treated with ultrasound guided percutaneous aspiration. The need for open surgical management is rare and includes chronic infection unresponsive to non-operative management and complicated acute infection such as perineal fistula formation. Open surgical management would require use of the operating room for both appropriate anesthesia and for the resources required to perform the more invasive perineal surgical dissection. Therefore, our clinical advisors believe a non-extensive O.R. designation is suitable for this procedure.

We analyzed claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code 0T9D0ZZ in MS–DRGs 981, 982, and 983. We found one case in MS–DRG 981 with an average length of stay of 8.0 days and average costs of $23,566 in the March 2020 update of the FY 2019 MedPAR file, and no cases in the September 2020 update of the FY 2020 MedPAR file. Although our claims analysis identified only one case reporting procedure code 0T9D0ZZ, our clinical advisors believe that these procedures would be more appropriately designated as Non-extensive procedures because they are more consistent with other procedures on the Non-extensive procedure code list.

Therefore, we are proposing to reassign procedure code 0T9D0ZZ from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for FY 2022.

11. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.D.13 of the preamble of this proposed rule, we are making Table 6B.—New Procedure Codes—FY 2022 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We also refer readers to the ICD–10 MS–DRG Version 38.1 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multi year project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization,

particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration.

In consideration of the PHE, we believe it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. Additional time is also necessary as we continue to develop our process and methodology. Therefore, we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

In this proposed rule, we are addressing requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or changing the designation from O.R. procedure to non-O.R. procedure. In this section of the rule we discuss the process that was utilized for evaluating the requests that were received for FY 2022 consideration. For each procedure, our clinical advisors considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a nonextensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of this rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In cases where we are proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also are proposing one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, if requestors included some or all of MS–DRGs 981 through 989 in their request or included MS–DRGs that require the presence of any O.R. procedure, we did not specifically address that aspect in summarizing their request or our response to the request in this section of this rule.

For procedures that would not typically require the resources of an operating room, our clinical advisors determined if the procedure should affect the MS–DRG assignment.

We received several requests to change the designation of specific ICD–10–PCS procedure codes from non-O.R. procedures to O.R. procedures, or to change the designation from O.R. procedures to non-O.R. procedures. In this section of this rule, we detail and respond to some of those requests. With regard to the remaining requests, our clinical advisors believe it is appropriate to consider these requests as part of our comprehensive review of the procedure codes as previously discussed.

b. O.R. Procedures to Non-O.R. Procedures

(1) Open Drainage of Subcutaneous Tissue and Fascia

One requestor identified the following ICD–10–PCS procedure code that describes the open drainage of right lower leg subcutaneous tissue and fascia, shown in the following table.

ICD-10-PCS Code	Code Description
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach

In the ICD–10 MS–DRG Version 38.1 Definitions Manual, this ICD–10–PCS procedure code is currently recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that this procedure consumes resources comparable to related ICD–10–PCS procedure code 0J9N00Z (Drainage of right lower leg subcutaneous tissue and fascia with drainage device, open approach) that describes the open drainage of right lower leg subcutaneous tissue and fascia with a drainage device, which is currently designated as a Non-O.R. procedure. The requestor stated that these comparable procedures should be recognized similarly for purposes of MS–DRG assignment.

During our review of this issue, we identified 21 ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia, shown in the following table that are clinically similar to ICD–10–PCS code 0J9N0ZZ, and are also designated as O.R.

procedures in the ICD–10 MS–DRG Version 38.1 Definitions Manual.

ICD-10-PCS Code	Code Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

We reviewed these procedures and our clinical advisors agree that procedures that describe the open drainage of subcutaneous tissue and fascia consume resources comparable to the related ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia with a drainage device that are currently designated as non-O.R. procedures. These procedures do not typically require the resources of an operating room, and are not surgical in nature. Therefore, we are proposing to remove the 22 codes listed in the following table from the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

ICD-10-PCS Code	Code Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach

ICD-10-PCS Code	Code Description
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

c. Non-O.R. Procedures to O.R. Procedures

(1) Percutaneous Introduction of Substance Into Cranial Cavity and Brain

One requestor identified ICD–10–PCS procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor recommended that this procedure be designated as an O.R. procedure because the procedure requires traversing the skull in order to place a substance within the cranial cavity or brain. The requestor noted that CMS disagreed with designating this procedure as an O.R. procedure last year in the absence of claims data; however, the requestor stated that because the skull must be opened by drilling or cutting a burr hole through the skull, this procedure warrants O.R. status similar to other transcranial procedures performed with an open or percutaneous approach that are classified as O.R. procedures.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure code XW0Q316 is currently designated as a non-O.R. procedure for purposes of MS–DRG assignment. We agree with the requestor that procedure code XW0Q316 describes a procedure that involves the creation of a burr hole in the skull. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58579 through 58580), we stated that, consistent with our annual process of assigning new procedure codes to MDCs and MS–DRGs, and designating a procedure as an O.R. or non-O.R. procedure, we reviewed the predecessor procedure code assignment. The predecessor code for procedure code XW0Q316 is procedure code 3E0Q3GC (Introduction of other therapeutic substance into cranial cavity and brain, percutaneous approach) which is designated as a non-O.R. procedure. In the absence of claims data, our clinical advisors also considered the indication for the specific procedure being described by the new procedure code, the treatment difficulty, and the resources utilized.

Upon further review and consideration, our clinical advisors agree that procedure code XW0Q316 describing a procedure that is performed by creating a burr hole in the skull warrants designation as an O.R. procedure consistent with other percutaneous procedures performed on the cranial cavity and brain body parts. Therefore, we are proposing to add this procedure code to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E- Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure, assigned to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

(2) Open Drainage of Maxilla and Mandible

One requestor identified three ICD–10–PCS procedure codes that describe the open drainage of maxilla or mandible that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The three procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0N9R0ZZ	Drainage of maxilla, open approach
0N9T0ZZ	Drainage of right mandible, open approach
0N9V0ZZ	Drainage of left mandible, open approach

The requestor stated that procedures that describe the open drainage of the maxilla or mandible should be designated as O.R. procedures because these procedures, indicated for diagnoses such as subperiosteal abscesses, are performed in the operating room under general anesthesia and involve making open incisions through muscle and stripping away the periosteum. The requestor identified procedure codes 0W950ZZ (Drainage of lower jaw, open approach) and 0W940ZZ (Drainage of upper jaw, open approach) that are currently designated as O.R. procedures. The requestor noted that ICD–10–PCS guidelines instruct that the procedure codes in Anatomical Regions, General, can be used when the procedure is performed on an anatomical region rather than a specific body part, or on the rare occasion when no information is available to support assignment of a code to a specific body part. The requestor stated that because bone is a specific body part in ICD–10–PCS, procedure codes should be assigned for subperiosteal drainage of mandible and maxilla bones from table 0N9, Drainage of Head and Facial Bones, instead of codes from table 0W9, Drainage of Anatomical Regions, General, when these procedures are performed. Therefore, the requestor stated that procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ should also be recognized as O.R. procedures for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors reviewed this issue and disagree that the procedures describing the open drainage of the maxilla or mandible are typically performed in the operating room under general anesthesia. Our clinical advisors state that these procedures can be done in an oral surgeon's office or an outpatient setting and are rarely performed in the inpatient setting. Our clinical advisors also state a correlation cannot be made between procedures performed in general anatomic regions and procedures performed in specific body parts because these procedures coded with the general anatomic regions body part represent a broader range of procedures that cannot be coded to a specific body part. Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ.

(3) Thoracoscopic Extirpation of Pleural Cavities

One requestor identified ICD–10–PCS procedure codes 0WC94ZZ (Extirpation of matter from right pleural cavity, percutaneous endoscopic approach) and 0WCB4ZZ (Extirpation of matter from left pleural cavity, percutaneous

endoscopic approach) that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor stated that these procedures should be designated as O.R. procedures because they are thoracoscopic procedures that are always performed in the operating room under general anesthesia. The requestor stated procedure codes 0W994ZZ (Drainage of right pleural cavity, percutaneous endoscopic approach) and 0W9B4ZZ (Drainage of left pleural cavity, percutaneous endoscopic approach) are currently designated as O.R. procedures, therefore procedure codes 0WC94ZZ and 0WCB4ZZ should also be recognized as O.R. procedures for purposes of MS–DRG assignment because they utilize the same resources.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0WC94ZZ and 0WCB4ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors reviewed this issue and disagree that procedure codes describing the thoracoscopic drainage of the pleural cavities should necessarily have the same designation as procedure codes describing the thoracoscopic extirpation of matter from the pleural cavities. We note that our review of the designation of ICD–10–PCS codes as an O.R. procedure or a non-O.R. procedure considers the resources used as well as whether that procedure should affect the MS–DRG assignment, and if so, in what way. Our clinical advisors state that thoracoscopic drainage of the pleural cavities is performed for distinct indications in clinically different scenarios. Our clinical advisors state that drainage is the process of taking out, or letting out, fluids and/or gases from a body part and is typically performed in the pleural cavity for indications such as congestive heart failure, infection, hemothorax and empyema. In contrast, the procedures describing the thoracoscopic extirpation of the pleural cavities are performed for a wider range of indications because the solid matter removed may be an abnormal byproduct of a biological function or a foreign body. Our clinical advisors note that the thoracoscopic extirpation of the pleural cavities is generally performed with other procedures such as heart transplant, lung transplant mechanical ventilation, and other major chest procedures and would not be the main reason for inpatient hospitalization or be considered the principal driver of resource expenditure.

Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0WC94ZZ and 0WCB4ZZ.

(4) Open Pleural Biopsy

One requestor identified ICD–10–PCS procedure codes 0BBN0ZX (Excision of right pleura, open approach, diagnostic) and 0BBP0ZX (Excision of left pleura, open approach, diagnostic), that describe an open pleural biopsy that the requestor stated are performed in the operating room with general anesthesia. The requestor also stated that procedure codes 0BBN0ZZ (Excision of right pleura, open approach) and 0BBP0ZZ (Excision of left pleura, open approach) describing open pleural biopsy for non-diagnostic purposes are justifiably designated as O.R. procedures. According to the requestor, these procedure codes describing an open pleural biopsy should be designated as O.R. procedures regardless of whether they are performed for diagnostic or therapeutic purposes.

We note that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description. In response to the requestor's suggestion that procedures performed for a pleural biopsy by an open approach, regardless of whether it is a diagnostic or therapeutic procedure, should be designated as an O.R. procedure, we examined procedure codes 0BBN0ZX, 0BBN0ZZ, 0BBP0ZX, and 0BBP0ZZ.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0BBN0ZZ and 0BBP0ZZ are currently designated as O.R. procedures, however, procedure codes 0BBN0ZX and 0BBP0ZX are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agree with the requestor that procedure codes 0BBN0ZX and 0BBP0ZX would typically require the resources of an operating room. Our clinical advisors also agree that procedure codes 0BBN0ZX and 0BBP0ZX would typically require the resources of an operating room. Therefore, we are proposing to add these 2 procedure codes to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS– DRG Index as O.R. procedures, assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System).

(5) Percutaneous Revision of Intraluminal Devices

One requestor identified five ICD–10–PCS procedure codes that describe the percutaneous revision of intraluminal vascular devices that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The five procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
02WY3DZ	Revision of intraluminal device in the great vessel, percutaneous approach
03WY3DZ	Revision of intraluminal device in upper artery, percutaneous approach
04WY3DZ	Revision of intraluminal device in lower artery, percutaneous approach
05WY3DZ	Revision of intraluminal device in upper vein, percutaneous approach
06WY3DZ	Revision of intraluminal device in lower vein, percutaneous approach

The requestor stated that the procedure codes that describe the percutaneous revision of intraluminal vascular devices within arteries, veins, and great vessels should be designated as O.R. procedures to compensate for the resources needed to perform these procedures. The requestor also stated procedures to reattach, realign, or otherwise revise intraluminal devices percutaneously require anesthesia, specialized equipment for intravascular visualization, significant skill, and time, therefore, it is important for these codes

to be designated with O.R. procedure status.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 02WY3DZ, 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We agree with the requestor that these five ICD–10–PCS procedure codes typically require the resources of an operating room. Therefore, to the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we are proposing to add code 02WY3DZ as an O.R. procedure assigned to MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System). We are also proposing to add codes 03WY3DZ, 04WY3DZ, 05WY3DZ, and 06WY3DZ as O.R. procedures assigned to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System).

(6) Occlusion of Left Atrial Appendage

One requestor identified nine ICD–10–PCS procedure codes that describe left atrial appendage closure (LAAC) procedures that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment in all instances. The nine procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
02L70CK	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	Occlusion of left atrial appendage, open approach
02L73CK	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	Occlusion of left atrial appendage with intraluminal device, percutaneous approach
02L73ZK	Occlusion of left atrial appendage, percutaneous approach
02L74CK	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	Occlusion of left atrial appendage, percutaneous endoscopic approach

The requestor stated that these procedures are currently designated as non-O.R. procedures that route to surgical MS–DRGs only when assigned in combination with a principal diagnosis within MDC 05 (Diseases and Disorders of the Circulatory System). The requestor stated these procedures should also be designated as O.R. procedures when assigned in combination with diagnoses outside of the circulatory system, such as sepsis or trauma, to compensate for the associated resource use, skill requirements, and device costs.

In the ICD–10 MS–DRG Version 38.1 Definitions Manual, the nine ICD–10–PCS procedure codes that describe left atrial appendage closure are currently recognized as non-O.R. procedures that affect the MS–DRG to which they are assigned. We refer readers to section II.D.5.d of the preamble of this proposed rule, where we address ICD–10–PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK that describe a LAAC procedure performed with an open approach. These codes were discussed in response to a request to reassign these codes to MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively) and, for the reasons discussed, we are proposing to maintain the assignment in MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with and without MCC, respectively) in MDC 05.

Our clinical advisors reviewed this related issue and believe the current designation of LAAC procedures as non-O.R. procedures that affect the assignment for MS–DRGs 273 and 274 is clinically appropriate to account for the subset of patients undergoing left atrial appendage closure specifically. LAAC is indicated and approved as a treatment option for patients diagnosed with atrial fibrillation, a heart rhythm disorder that can lead to cardiovascular blood clot formation, who are also at increased risk for stroke. LAAC procedures block off the left atrial appendage to prevent emboli that may form in the left atrial appendage from exiting and traveling to other sites in the vascular system, thereby preventing the occurrence of ischemic stroke and systemic thromboembolism. The ICD–10–CM diagnosis codes used to report atrial fibrillation are currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System). Our clinical advisors believe that circumstances in which a patient is admitted for a principal diagnosis outside of MDC 05 and a left atrial appendage closure is performed as the only surgical procedure in the same admission are infrequent, and if they do occur, the LAAC procedure would not be a significant contributing factor in the increased intensity of resources needed for facilities to manage these complex cases. Our clinical advisors state LAAC procedures generally do not require the resources of an operating room. LAAC procedures are most often performed percutaneously in settings such as cardiac catheterization laboratories and take approximately one hour. When performed with an open approach or percutaneous endoscopic approach, these procedures share similar factors such as complexity, and resource

utilization with all other LAAC procedures. Therefore, we are proposing to maintain the current designation of ICD–10–PCS procedure codes 02L70CK, 02L70DK, 02L70ZK, 02L73CK, 02L73DK, 02L73ZK, 02L74CK, 02L74DK, and 02L74ZK as non-O.R. procedures affecting the MS–DRGs to which they are assigned.

(7) Arthroscopic Drainage of Joints

One requestor identified six ICD–10–PCS procedure codes that describe the percutaneous endoscopic drainage of joints that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0S9C4ZZ	Drainage of right knee joint, percutaneous endoscopic approach
0S9D4ZZ	Drainage of left knee joint, percutaneous endoscopic approach
0S994ZZ	Drainage of right hip joint, percutaneous endoscopic approach
0S9B4ZZ	Drainage of left hip joint, percutaneous endoscopic approach
0R9J4ZZ	Drainage of right shoulder joint, percutaneous endoscopic approach
0R9K4ZZ	Drainage of left shoulder joint, percutaneous endoscopic approach

The requestor stated that these procedures should be designated as O.R. procedures because procedures describing the arthroscopic drainage of major joints such as knee, hip, and shoulder are performed in the operating room under general anesthesia. The requestor stated these procedures are indicated for conditions such as symptomatic septic/pyogenic arthritis, which can require inpatient admission for intravenous antibiotics and arthroscopic drainage to resolve infection. Therefore, the requestor stated it is reasonable for these arthroscopic procedures to be designated as O.R. procedures to compensate for operating room resources.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors reviewed this issue and disagree that procedures describing the percutaneous endoscopic drainage of major joints such as knee, hip, and shoulder are typically performed in the operating room under general anesthesia. With development of better instrumentation and surgical techniques, many patients now have arthroscopic procedures performed in an outpatient setting and return home several hours after the procedure. Our clinical advisors also state the percutaneous endoscopic drainage of joints can be performed using local or regional anesthesia, and general anesthesia is not always required. In cases where the patient is admitted for diagnoses such as septic/pyogenic arthritis, as identified by the requestor, the requirement for intravenous antibiotics would be the main reason for admission because the percutaneous endoscopic drainage procedure could be done as an outpatient. Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0S9C4ZZ, 0S9D4ZZ, 0S994ZZ, 0S9B4ZZ, 0R9J4ZZ, and 0R9K4ZZ.

(8) Arthroscopic Irrigation of Joints

One requestor identified ICD–10–PCS procedure codes 3E1U48X (Irrigation of joints using irrigating substance, percutaneous endoscopic approach, diagnostic) and 3E1U48Z (Irrigation of joints using irrigating substance, percutaneous endoscopic approach) that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor stated that these procedures should be designated as O.R. procedures because the arthroscopic irrigation of joints such as knee, hip, and shoulder is performed in the operating room under general anesthesia. The requestor states procedure codes 3E1U48X and 3E1U48Z are used to describe surgical joint irrigations in the absence of more definitive procedures, therefore procedure codes 3E1U48X and 3E1U48Z should be recognized as O.R. procedures for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 3E1U48X and 3E1U48Z are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors reviewed this issue and disagree that procedure codes describing the arthroscopic irrigation of joints should be designated as O.R. procedures. Our clinical advisors note the arthroscopic irrigation of joints is rarely performed independently as a standalone procedure in the inpatient setting to be considered the principal driver of resource expenditure in those admissions. Instead, the arthroscopic irrigation of joints is generally performed with other definitive procedures such as debridement or synovectomy. We note that in the operative note sent by the requestor to support the requested change in O.R. status, the arthroscopic irrigation of the joint was performed along with a surgical debridement procedure. Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 3E1U48X and 3E1U48Z.

(9) Percutaneous Reposition With Internal Fixation

One requestor identified four ICD–10–PCS procedure codes describing procedures performed on the sacroiliac and hip joints that involve percutaneous repositioning with internal fixation that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment but warrant an O.R. designation. The procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0SS734Z	Reposition right sacroiliac joint with internal fixation device, percutaneous approach
0SS834Z	Reposition left sacroiliac joint with internal fixation device, percutaneous approach
0SS934Z	Reposition right hip joint with internal fixation device, percutaneous approach
0SSB34Z	Reposition left hip joint with internal fixation device, percutaneous approach

Our clinical advisors reviewed the procedures described by these four procedure codes and agree that these percutaneous reposition procedures involving internal fixation in the sacroiliac and hip joint warrant an O.R. designation. They noted that these procedures are major operations that would require the resources of an operating room, involve a higher level of technical complexity and a greater utilization of hospital resources.

Therefore, we are proposing to add the two procedure codes describing percutaneous reposition of the sacroiliac joint with internal fixation procedures (0SS734Z and 0SS834Z) to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively). We are also proposing to add the two procedure codes describing percutaneous reposition of the hip joint with internal fixation procedures (0SS934Z and 0SSB34Z) to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) in MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

(10) Open Insertion and Removal of Spacer Into Shoulder Joint

One requestor identified four ICD–10–PCS procedure codes describing procedures performed on the shoulder joint that involve the insertion or removal of a spacer by an open approach that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment. The procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0RHK08Z	Insertion of spacer into left shoulder joint, open approach
0RHJ08Z	Insertion of spacer into right shoulder joint, open approach
0RPK08Z	Removal of spacer from left shoulder joint, open approach
0RPJ08Z	Removal of spacer from right shoulder joint, open approach

According to the requestor, insertion and removal of joint spacers from the hips and knees are designated with an O.R. procedure status and although similar procedures performed on the shoulder joint may be performed less frequently, these procedures warrant an O.R. designation because they are performed in the operating room under general anesthesia. During our review, we noted that the following procedure codes describing procedures performed on the shoulder joint that involve the insertion or removal of a spacer by a percutaneous endoscopic approach are also not recognized as O.R. procedures for purposes of MS–DRG assignment.

ICD-10-PCS Code	Code Description
0RPJ48Z	Removal of spacer from right shoulder joint, percutaneous endoscopic approach
0RPK48Z	Removal of spacer from left shoulder joint, percutaneous endoscopic approach
0RHJ48Z	Insertion of spacer into right shoulder joint, percutaneous endoscopic approach
0RHK48Z	Insertion of spacer into left shoulder joint, percutaneous endoscopic approach

Our clinical advisors reviewed the procedures described by these eight procedure codes and agree that these procedures involving the insertion or removal of a spacer in the shoulder joint with an open or percutaneous endoscopic approach warrant an O.R. designation. They noted that the insertion of a spacer is typically performed to treat an infection at the site of a previously placed prosthesis and the removal of a spacer is typically performed once the infection is healed and the site is ready for a new prosthetic replacement or to exchange for a new spacer if the infection is not yet healed.

Therefore, we are proposing to add the listed procedure codes describing the insertion or removal of spacer in the shoulder joint to the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 510, 511, and 512 (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

(11) Open/Percutaneous Extirpation of Jaw

One requestor identified four ICD–10–PCS procedure codes that describe the extirpation of matter from the upper or lower jaw that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The four procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0WC40ZZ	Extirpation of matter from upper jaw, open approach
0WC44ZZ	Extirpation of matter from upper jaw, percutaneous endoscopic approach
0WC50ZZ	Extirpation of matter from lower jaw, open approach
0WC54ZZ	Extirpation of matter from lower jaw, percutaneous endoscopic approach

The requestor stated that the procedure codes that describe the extirpation of matter from the upper or lower jaw by an open or percutaneous endoscopic approach should be designated as O.R. procedures. The requestor stated these procedures would commonly be performed under general anesthesia and require the resources of an operating room. The requestor also stated that these ICD–10–PCS codes were specifically created to describe the surgical evacuation of solid matter from deep jaw structures therefore, it is important for these codes to be designated with O.R. procedure status.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0WC40ZZ, 0WC44ZZ, 0WC50ZZ, 0WC54ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We agree with the requestor that these four ICD–10–PCS procedure codes typically require the resources of an operating room. Therefore, to the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we are proposing to add codes 0WC40ZZ, 0WC44ZZ, 0WC50ZZ, 0WC54ZZ as O.R. procedures assigned to MS–DRGs 143, 144 and 145 (Other Ear, Nose, Mouth and Throat O.R. procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat).

(12) Open Extirpation of Subcutaneous Tissue and Fascia

One requestor identified 22 ICD–10–PCS procedure codes that describe the open extirpation of matter from the subcutaneous tissue and fascia that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The 22 procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0JC00ZZ	Extirpation of matter from scalp subcutaneous tissue and fascia, open approach
0JC10ZZ	Extirpation of matter from face subcutaneous tissue and fascia, open approach
0JC40ZZ	Extirpation of matter from right neck subcutaneous tissue and fascia, open approach
0JC50ZZ	Extirpation of matter from left neck subcutaneous tissue and fascia, open approach
0JC60ZZ	Extirpation of matter from chest subcutaneous tissue and fascia, open approach
0JC70ZZ	Extirpation of matter from back subcutaneous tissue and fascia, open approach
0JC80ZZ	Extirpation of matter from abdomen subcutaneous tissue and fascia, open approach
0JC90ZZ	Extirpation of matter from buttocks subcutaneous tissue and fascia, open approach
0JCB0ZZ	Extirpation of matter from perineum subcutaneous tissue and fascia, open approach
0JCC0ZZ	Extirpation of matter from pelvic region subcutaneous tissue and fascia, open approach
0JCD0ZZ	Extirpation of matter from right upper arm subcutaneous tissue and fascia, open approach
0JCF0ZZ	Extirpation of matter from left upper arm subcutaneous tissue and fascia, open approach
0JCG0ZZ	Extirpation of matter from right lower arm subcutaneous tissue and fascia, open approach
0JCH0ZZ	Extirpation of matter from left lower arm subcutaneous tissue and fascia, open approach
0JCJ0ZZ	Extirpation of matter from right hand subcutaneous tissue and fascia, open approach
0JCK0ZZ	Extirpation of matter from left hand subcutaneous tissue and fascia, open approach
0JCL0ZZ	Extirpation of matter from right upper leg subcutaneous tissue and fascia, open approach
0JCM0ZZ	Extirpation of matter from left upper leg subcutaneous tissue and fascia, open approach
0JCN0ZZ	Extirpation of matter from right lower leg subcutaneous tissue and fascia, open approach
0JCP0ZZ	Extirpation of matter from left lower leg subcutaneous tissue and fascia, open approach
0JCQ0ZZ	Extirpation of matter from right foot subcutaneous tissue and fascia, open approach
0JCR0ZZ	Extirpation of matter from left foot subcutaneous tissue and fascia, open approach

The requestor stated that procedure codes that describe the open extirpation of matter from the subcutaneous tissue and fascia should be designated as O.R. procedures because these procedures are performed through open incisions with direct visualization of subcutaneous tissue and fascia in the operating room under general anesthesia. The requestor noted procedure codes that describe the open drainage of subcutaneous tissue and fascia and use comparable resources are currently designated as O.R. procedures. The requestor noted that root operation ''Drainage'' is assigned when fluid is drained; and root operation of ''Extirpation'' is assigned when any of the substance evacuated is solid. The requestor stated whether the evacuated substance is fluid, gelatinous, or solid, a procedure involving an open incision with direct visualization of subcutaneous tissue and fascia for evacuation of substances should be classified as an O.R. procedure. Therefore, the requestor stated that these procedures should also be recognized as O.R. procedures for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, the 22 ICD–10–PCS procedure codes listed in the table are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. While we disagree that drainage procedures are comparable to extirpation procedures, we agree with the requestor that these 22 ICD–10–PCS procedure codes typically require the resources of an operating room. Our clinical advisors state that drainage is the process of taking out, or letting out, fluids and/or gases from a body part and is typically performed for indications such as abscess, infection, and other systemic conditions. In contrast, extirpation procedures are performed for a wider range of indications because the solid matter removed may be an abnormal byproduct of a biological function or a retained foreign body. Therefore, to the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we are proposing to add the 22 ICD–10–PCS listed previously as O.R. procedures assigned to MS–DRGs 579, 580 and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs).

(13) Open Revision and Removal of Devices From Subcutaneous Tissue and Fascia

One requestor identified six ICD–10–PCS procedure codes describing open revision and removal of neurostimulator generators, monitoring devices, and totally implantable vascular access devices (TIVADs) procedures that are not currently designated as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0JPT0MZ	Removal of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JPT02Z	Removal of monitoring device from trunk subcutaneous tissue and fascia, open approach
0JPT0WZ	Removal of totally implantable vascular access device from trunk subcutaneous tissue and fascia, open approach
0JWT0MZ	Revision of stimulator generator from trunk subcutaneous tissue and fascia, open approach
0JWT0WZ	Revision of totally implantable vascular access device from trunk subcutaneous tissue and fascia, open approach
0JWT03Z	Revision of infusion device in trunk subcutaneous tissue and fascia, open approach

The requestor stated that although removal of these devices is often performed in outpatient surgery, device complications can require removal or revision during inpatient hospitalizations. The requestor indicated it is reasonable for these open procedures to be designated as O.R. procedures to compensate for operating room resources during such inpatient stays.

Our clinical advisors reviewed this request and do not agree that these procedures warrant an O.R. designation. They noted that these procedures are generally performed in the outpatient setting and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. Therefore, we are proposing to maintain the current non-O.R. designation for procedure codes 0JPT0MZ, 0JPT02Z, 0JPT0WZ, 0JWT0MZ, 0JWT0WZ, and 0JWT03Z for FY 2022.

(14) Open Insertion of Feeding Device

One requestor identified ICD–10–PCS procedure code 0DHA0UZ (Insertion of feeding device into jejunum, open approach) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor stated the open insertion of a feeding device into the jejunum should be designated as an O.R. procedure because this procedure is performed in the operating room under general anesthesia. The requestor noted comparable procedure code 0DH60UZ (Insertion of feeding device into stomach, open approach) is currently designated as an O.R. procedure. Therefore, the requestor stated that procedure code 0DHA0UZ should also be recognized as an O.R. procedure for purposes of MS–DRG assignment.

Our analysis of this issue confirmed that in the ICD–10 MS–DRG Version 38.1 Definitions Manual, for purposes of MS–DRG assignment, 0DHA0UZ is recognized as a non-O.R. procedure and 0DH60UZ is currently recognized as an O.R. procedure. In reviewing this request, we also identified the following four related codes:

ICD-10-PCS Code	Code Description
0DH50UZ	Insertion of feeding device into esophagus, open approach
0DH80UZ	Insertion of feeding device into small intestine, open approach
0DH90UZ	Insertion of feeding device into duodenum, open approach
0DHB0UZ	Insertion of feeding device into ileum, open approach

In the ICD–10 MS–DRGs Version 38.1, these four ICD–10–PCS codes are currently recognized as non-O.R. procedure for purposes of MS–DRG assignment. While we agree with the requestor that procedures describing the open insertion of a feeding device into the jejunum are comparable to procedures describing the open insertion of a feeding device into the stomach, we do not agree that these procedures should be designated as O.R. procedures. Our clinical advisors state the procedures that describe the open insertion of a feeding device into the jejunum or the stomach should instead have the same designation as the related ICD–10–PCS procedure codes that describe the open insertion of a feeding device into the esophagus, small intestine, duodenum and ileum that are currently designated as non-O.R. procedures.

With advancements in procedural techniques, feeding devices are most commonly placed using a percutaneous endoscopic approach. Our clinical advisors state feeding devices are usually not placed using an open surgical approach; this approach is

generally only used if the patient requires another surgical procedure at the same time. When placed at the same time as another surgical procedure, our clinical advisors state the surgical procedure, as the main determinant of resource use for those cases, should drive the MS–DRG assignment, not the procedure that describes the open insertion of a feeding device. For these reasons, our clinical advisors state procedures that describe the open insertion of a feeding device in the gastrointestinal system should all have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence.

Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure code 0DHA0UZ. We are also proposing to remove ICD–10–PCS procedure code 0DH60UZ from the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure. Under this proposal, this procedure would no longer impact MS–DRG assignment.

(15) Laparoscopic Insertion of Feeding Tube

One requestor identified ICD–10–PCS procedure codes 0DH64UZ (Insertion of feeding device into stomach, percutaneous endoscopic approach) and 0DHA4UZ (Insertion of feeding device into jejunum, percutaneous endoscopic approach) that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor stated the procedures describing the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum should be designated as O.R. procedures because these procedures are performed in the operating room under general anesthesia. The requestor stated all laparoscopic procedures, regardless if they are diagnostic or therapeutic, should be classified as O.R. procedures to compensate for operating room resources.

Our analysis of this issue confirmed that in the ICD–10 MS–DRG Version 38.1 Definitions Manual, 0DH64UZ and 0DHA4UZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. In reviewing this request, we also identified the following four related codes:

ICD-10-PCS Code	Code Description
0DH54UZ	Insertion of feeding device into esophagus, percutaneous endoscopic approach
0DH84UZ	Insertion of feeding device into small intestine, percutaneous endoscopic approach
0DH94UZ	Insertion of feeding device into duodenum, percutaneous endoscopic approach
0DHB4UZ	Insertion of feeding device into ileum, percutaneous endoscopic approach

In the ICD–10 MS–DRGs Version 38.1, these four ICD–10–PCS codes are currently recognized as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors reviewed this request and do not agree that unilaterally all laparoscopic procedures should be designated as O.R. procedures. While the procedural approach is an important consideration in the designation of a procedure, there are other clinical factors such as the site of procedure, the procedure complexity, and resource utilization that should also be considered. In this regard, our clinical advisors indicated that codes 0DH64UZ and 0DHA4UZ describing the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum, do not require the resources of an operating room, are not surgical in nature, and are generally performed in the outpatient setting. The percutaneous endoscopic insertion of a feeding device also does not require general anesthesia. As opposed to being rendered unconscious, patients can receive a local anesthetic (usually a lidocaine spray), an intravenous (IV) pain reliever, and a mild sedative if needed. Patients receiving these devices usually return home the same day after placement, unless they are in the hospital for treatment of another condition.

Our clinical advisors state the percutaneous endoscopic insertion of a feeding device into the stomach or the jejunum is comparable to the related ICD–10–PCS procedure codes that describe the insertion of feeding devices of other gastrointestinal system body parts that are currently designated as non-O.R. procedures. Our clinical advisors believe all procedures that describe the percutaneous endoscopic insertion of a feeding device in the gastrointestinal system should continue to have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence. Therefore, for the reasons discussed, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0DH64UZ and 0DHA4UZ.

(16) Endoscopic Fragmentation and Extirpation of Matter of Urinary Tract

One requestor sent two separate but related requests related to endoscopic procedures performed in the urinary system. With regard to the first request, the requestor identified six ICD–10–PCS procedure codes that describe endoscopic fragmentation in the kidney pelvis, ureter, bladder, and bladder neck that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0TF38ZZ	Fragmentation in right kidney pelvis, via natural or artificial opening, endoscopic
0TF48ZZ	Fragmentation in left kidney pelvis, via natural or artificial opening, endoscopic
0TF68ZZ	Fragmentation in right ureter, via natural or artificial opening, endoscopic
0TF78ZZ	Fragmentation in left ureter, via natural or artificial opening, endoscopic
0TFB8ZZ	Fragmentation in bladder, via natural or artificial opening, endoscopic
0TFC8ZZ	Fragmentation in bladder neck, via natural or artificial opening, endoscopic

The requestor stated that these procedures should be designated as O.R. procedures because procedures such as the endoscopic fragmentation of calculi within the kidney pelvis, ureter, bladder, and bladder neck are performed in the operating room under anesthesia. The requestor stated that procedures that describe the endoscopic extirpation of calculi from the kidney pelvis or ureter use comparable resources, and are designated as O.R. procedures. Therefore, the requestor asserted it is reasonable that procedure codes that describe endoscopic fragmentation in kidney pelvis, ureter, bladder, and bladder neck also be designated as O.R. procedures.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0TF38ZZ, 0TF48ZZ, 0TF68ZZ, 0TF78ZZ, 0TFB8ZZ, and 0TFC8ZZ are designated as non-O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors reviewed this issue and disagree that procedures describing the endoscopic fragmentation of calculi within the kidney pelvis, ureter, bladder, and bladder neck are typically performed in the operating room. In endoscopic fragmentation procedures in the kidney pelvis, ureter, bladder, and bladder neck, the scope is passed through a natural or artificial orifice. The procedure is not surgical in nature and involves no skin incisions. With advancements in scope size, deflection capabilities, video imaging, and instrumentation, many patients now have these endoscopic urinary procedures performed in an outpatient setting, instead of the inpatient setting. Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0TF38ZZ, 0TF48ZZ, 0TF68ZZ, 0TF78ZZ, 0TFB8ZZ, and 0TFC8ZZ.

In the second request, the requestor also identified two ICD–10–PCS procedure codes that describe endoscopic extirpation of matter from the bladder and bladder neck that the requestor stated are also currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The two procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0TCB8ZZ	Extirpation of matter from bladder via natural or artificial opening, endoscopic
0TCC8ZZ	Extirpation of matter from bladder neck via natural or artificial opening, endoscopic

The requestor stated that these procedures also should be designated as O.R. procedures because they performed in the operating room under anesthesia.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0TCB8ZZ and 0TCC8ZZ are currently designated as a non-O.R. procedure for purposes of MS–DRG assignment. To review the request to designate 0TCB8ZZ and 0TCC8ZZ as O.R. procedures and in response to the requestor's suggestion that resource consumption is comparable in procedures describing endoscopic fragmentation in the urinary system and procedures describing the endoscopic extirpation in the urinary system, we examined the following procedure codes:

ICD-10-PCS Code	Code Description
0TC08ZZ	Extirpation of matter from right kidney, via natural or artificial opening endoscopic
0TC18ZZ	Extirpation of matter from left kidney, via natural or artificial opening endoscopic
0TC38ZZ	Extirpation of matter from right kidney pelvis, via natural or artificial opening endoscopic
0TC48ZZ	Extirpation of matter from left kidney pelvis, via natural or artificial opening endoscopic
0TC68ZZ	Extirpation of matter from right ureter, via natural or artificial opening endoscopic
0TC78ZZ	Extirpation of matter from left ureter, via natural or artificial opening endoscopic

In the ICD–10 MS–DRG Version 38.1 Definitions Manual, these six ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment. Our clinical advisors indicated that these procedures are not surgical in nature. In endoscopic extirpation procedures, the scope enters the urinary tract through the urethra, which is the tube that carries urine out of the body, or through an artificial orifice. Our clinical advisors state the urinary system is one conduit so the scope continues to pass through the urethra, bladder, and into the ureter or kidney (if necessary) to access the stone. For that reason, the procedures describing endoscopic extirpation from a urinary body part should all have the same non-O.R. designation in the ICD–10 MS–DRGs Version 39 for coherence.

Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0TCB8ZZ and 0TCC8ZZ. We are also proposing to remove ICD–10–PCS procedure codes 0TC08ZZ, 0TC18ZZ, 0TC38ZZ, 0TC48ZZ, 0TC68ZZ, and 0TC78ZZ from the FY 2022 ICD–10 MS–DRG Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

(17) Endoscopic Removal of Ureteral Stent

One requestor identified ICD–10–PCS procedure code 0TP98DZ (Removal of intraluminal device from ureter, via natural or artificial opening endoscopic) that the requestor stated is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that this procedure warrants an O.R. designation because the procedure code describes a procedure that is performed in the operating room with anesthesia. The requestor stated that while most ureteral stents can be removed by string, some complicated cases require endoscopic removal using forceps in the operating room under general anesthesia and may be performed during inpatient stays precipitated by severe urinary tract infection, sepsis, or urinary obstructions. The requestor asserted that procedure codes for insertion of ureteral stent(s) via a ureteroscopic, endoscopic approach have been justifiably designated as O.R. procedures because they are performed in the O.R. under anesthesia. Therefore, the requestor suggested it is reasonable for endoscopic removal of the stent to be designated with OR procedure status to compensate for operating room resources and anesthesia.

Our clinical advisors reviewed this procedure and do not agree that it warrants an O.R. designation. They noted that this procedure is generally not the focus of the admission when it is performed and does not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. Therefore, we are proposing to maintain the current non-O.R. designation for procedure code 0TP98DZ for FY 2022.

(18) Endoscopic/Transorifice Inspection of Ureter

One requestor identified ICD–10–PCS procedure code 0TJ98ZZ (Inspection of ureter, via natural or artificial opening endoscopic), that describes procedures involving endoscopic viewing of the ureter that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment.

The requestor stated this ureteroscopy procedure is performed in the operating room with anesthesia. According to the requestor, the inspection of ureter procedure code is assigned when obstruction is found during the ureteroscopy and procedures to break up (fragmentation), remove calculi (extirpation), or place a ureteral stent cannot be performed.

Our clinical advisors reviewed this procedure and disagree that it warrants an O.R. designation. They noted that this procedure typically does not require hospitalization and is generally not the reason for the patient's admission since it is often performed in connection with another O.R. procedure when it is performed. Therefore, we are proposing to maintain the current non-O.R. designation for procedure code 0TJ789ZZ for FY 2022.

(19) Endoscopic Biopsy of Ureter and Kidney

One requestor identified six ICD–10–PCS procedure codes that describe endoscopic biopsy procedures performed on the ureter and kidney structures that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. According to the requestor, regardless of whether it is a diagnostic or therapeutic procedure, these procedures should be designated as O.R. procedures because the procedures utilize operating room, anesthesia and recovery room resources. The requestor stated that after the surgeon places the scope into the bladder that ureteral orifices must be identified and instruments carefully navigated to obtain excisional biopsies from within the ureter or further within the kidney.

The six procedure codes are listed in the following table.

ICD-10-PCS Code	Code Description
0TB08ZX	Excision of right kidney, via natural or artificial opening, endoscopic, diagnostic
0TB18ZX	Excision of left kidney, via natural or artificial opening, endoscopic, diagnostic
0TB38ZX	Excision of right kidney pelvis, via natural or artificial opening, endoscopic, diagnostic
0TB48ZX	Excision of left kidney pelvis, via natural or artificial opening, endoscopic, diagnostic
0TB68ZX	Excision of right ureter, via natural or artificial opening, endoscopic, diagnostic
0TB78ZX	Excision of left ureter, via natural or artificial opening, endoscopic, diagnostic

We note that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description.

Our clinical advisors do not agree that endoscopic biopsy procedures performed on the ureter and kidney structures warrant an O.R. designation. They stated these procedures are typically not the focus for the patient's admission and are frequently performed in conjunction with another O.R. procedure. Therefore, we are proposing to maintain the current non-O.R. designation for procedure codes 0TB08ZX, 0TB18ZX, 0TB38ZX, 0TB48ZX, 0TB68ZX, and 0TB78ZX for FY 2022.

(20) Transorifice Insertion of Ureteral Stent

One requestor identified three ICD–10–PCS procedure codes that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor suggested that the procedure described by these procedure codes warrants an O.R. designation because it involves the insertion of an indwelling ureteral stent through a nephrostomy with image-guidance in the interventional radiology suite. According to the requestor, image-guided technology now allows placement of ureteral stents through nephrostomy tracts. The requestor stated this procedure may or may not be performed in the operating room, however, it involves placement of device(s), interventional radiology resources, sedation, and continuous monitoring of vital signs. The three procedure codes are shown in the following table.

ICD-10-PCS Code	Code Description
0T767DZ	Dilation of right ureter with intraluminal device, via natural or artificial opening
0T777DZ	Dilation of left ureter with intraluminal device, via natural or artificial opening
0T787DZ	Dilation of bilateral ureters with intraluminal device, via natural or artificial opening

Our clinical advisors reviewed this request and do not agree that this procedure warrants an O.R. designation. They noted that this procedure is not surgical in nature, does not require the resources of an operating room and is not a technically complex procedure requiring increased hospital resources. Therefore, we are proposing to maintain the current non-O.R. designation for procedure codes 0T767DZ, 0T777DZ, and 0T787DZ for FY 2022.

(21) Percutaneous Insertion of Ureteral Stent

One requestor identified three ICD–10–PCS procedure codes that the requestor stated are not recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor suggested that the procedure described by these procedure codes warrants an O.R. designation because the procedure is typically performed following a failed ureteral stent insertion procedure in the operating room, which can only be reported as a cystoscopy or ureteroscopy, neither of which are designated as O.R. procedures. According to the requestor, percutaneous ureteral stenting through the abdominal wall is subsequently performed in an interventional radiology suite with image-guidance, sedation, and continuous vital sign monitoring. The three procedure codes are shown in the following table.

ICD-10-PCS Code	Code Description
0T763DZ	Dilation of right ureter with intraluminal device, percutaneous approach
0T773DZ	Dilation of left ureter with intraluminal device, percutaneous approach
0T783DZ	Dilation of bilateral ureters with intraluminal device, percutaneous approach

Our clinical advisors reviewed this request and do not agree that the procedure warrants an O.R. designation. They noted that this procedure is not surgical in nature, does not involve technical complexity or require the resources of an operating rom. Therefore, we are proposing to maintain the current non-O.R. designation for procedure codes 0T763DZ, 0T773DZ, and 0T783DZ for FY 2022.

(22) Endoscopic Dilation of Urethra

One requestor identified ICD–10–PCS procedure code 0T7D8DZ (Dilation of urethra with intraluminal device, via natural or artificial opening endoscopic) that the requestor stated is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that this procedure warrants an O.R. designation because the procedure code describes a procedure that utilizes the UroLift® System, a minimally invasive technology to treat lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH). According to the requestor, the technology is placed endoscopically within the prostatic urethra in the operating room under anesthesia.

Our clinical advisors reviewed this request and do not agree that the procedure warrants an O.R. designation. They noted that this procedure is performed without incision, resection or thermal injury to the prostate and is primarily performed in the outpatient setting. It is generally not the cause for the patient's admission and utilization of resources when it is performed. Therefore, we are proposing to maintain the current non-O.R. designation for procedure code 00T7D8DZ for FY 2022.

(23) Open Repair of Scrotum

One requestor identified ICD–10–PCS procedure code 0VQ50ZZ (Repair scrotum, open approach) that the requestor stated is not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that this procedure warrants an O.R. designation because it involves repair of scrotal tissue deeper than the skin with direct visualization and utilizes general anesthesia in the operating room.

Our clinical advisors do not agree that open repair of the scrotum merits an O.R. designation. They stated this procedure would not typically require the resources of an operating room and would generally not be a contributing factor impacting hospital resource use during the patient's admission when it is performed. Therefore, we are proposing to maintain the current non-O.R. designation for procedure code 0VQ50ZZ for FY 2022.

(24) Open Drainage of Vestibular Gland

One requestor identified ICD–10–PCS procedure code 0U9L0ZZ (Drainage of vestibular gland, open approach) that describes a procedure commonly performed for the treatment of an abscess that the requestor stated is performed in the operating room under general anesthesia and therefore warrants an O.R designation. The requestor stated this procedure is comparable to the procedure described by procedure code 0UBL0ZZ (Excision of vestibular gland, open approach) which is currently designated as an O.R. procedure.

During our review of procedure code 0U9L0ZZ, we also examined procedure codes 0U9L0ZX (Drainage of vestibular gland, open approach, diagnostic), 0U9LXZX (Drainage of vestibular gland, external approach, diagnostic), and 0UBL0ZZ. Separately, we reviewed procedure code 0T9D0ZZ (Drainage of urethra, open approach) because it represents the male equivalent of the female procedure described by procedure code 0U9L0ZZ.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure codes 0T9D0ZZ, 0U9L0ZX, 0U9LXZX, and 0UBL0ZZ are currently designated as O.R. procedures, however, procedure code 0U9L0ZZ is not recognized as an O.R. procedure for purposes of MS–DRG assignment. We examined procedure code 0U9L0ZZ and do not believe this drainage procedure warrants an O.R. designation, nor do we agree that this drainage of the vestibular gland procedure (0U9L0ZZ) is comparable to an excision of the vestibular gland procedure (0UBL0ZZ), which is currently designated as an O.R. procedure.

In the ICD–10–PCS classification, drainage is defined as taking or letting out fluids and/or gases from a body part and excision is defined as cutting out or off, without replacement, a portion of a body part. Therefore, the classification specifically defines and distinguishes the underlying objectives of each distinct procedure. Our clinical advisors stated a drainage procedure is frequently performed in the outpatient setting and is generally not the cause for the patient's admission and utilization of resources when it is performed. Drainage of the vestibular gland, also known as Bartholin's glands, is typically indicated when a cyst or abscess is present and may or may not involve the placement of a Word catheter. Conversely, excision of the vestibular gland is not considered an office-based procedure and is generally reserved for a vulvar mass or for patients who have not responded to more conservative attempts to create a drainage tract. In addition, after review, our clinical advisors recommended changing the O.R. status for procedure codes 0U9L0ZX and 0U9LXZX from O.R. to non-O.R. for similar reasons. These procedures do not typically require the resources of an operating room.

Therefore, we are proposing to remove procedure codes 0U9L0ZX and 0U9LXZX from the FY 2022 ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E- Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedure codes would no longer impact MS–DRG assignment. We refer the reader to section II.D.10 of the preamble of this proposed rule for further discussion related to procedure code 0T9D0ZZ.

(25) Transvaginal Repair of Vagina

One requestor identified ICD–10–PCS procedure code 0UQG7ZZ (Repair vagina, via natural or artificial opening) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor stated that procedures described by this code such as the non-obstetric transvaginal repair of the vaginal cuff and the non-obstetric transvaginal repair of vaginal lacerations should be designated as O.R. procedures because these procedures are performed in the operating room under general anesthesia. The requestor noted procedure codes 0USG7ZZ (Reposition vagina, via natural or artificial opening), 0UBG7ZZ (Excision of vagina, via natural or artificial opening), and 0UQG8ZZ (Repair vagina, via natural or artificial opening endoscopic) are currently designated as O.R. procedures, therefore procedure code 0UQG7ZZ should also be recognized as an O.R. procedure for purposes of MS–DRG assignment.

In the ICD–10 MS–DRGs Definitions Manual Version 38.1, procedure code 0UQG7ZZ is currently designated as a non-O.R. procedure for purposes of MS–DRG assignment. Our clinical advisors reviewed this issue and disagree that a correlation can be made between procedures described as the transvaginal repair of the vagina and the procedures described by ICD–10–PCS codes 0USG7ZZ, 0UBG7ZZ, and 0UQG8ZZ. The root operation ''repair'' represents a broad range of procedures for restoring the anatomic structure of a body part such as suture of lacerations, while the root operations ''reposition,'' and ''excision'' define procedures with more

distinct objectives. Also the approach ''via natural or artificial opening'', for example, transvaginal, is defined as the entry of instrumentation through a natural or artificial external opening to reach the site of the procedure while the ''via natural or artificial opening endoscopic approach'' is defined as the entry of instrumentation (for example a scope) through a natural or artificial external opening to both reach and visualize the site of the procedure. Our clinical advisors also disagree that procedures described as the transvaginal repair of the vagina are typically performed in the operating room under general anesthesia. Our clinical advisors state transvaginal repair can be performed using regional anesthesia, used to numb only the area of the body that requires surgery instead of rendering the patient unconscious. Therefore, for the reasons described, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure code 0UQG7ZZ.

(26) Percutaneous Tunneled Vascular Access Devices

One requestor identified ten ICD–10–PCS procedure codes describing percutaneous insertion of tunneled vascular access devices into various body parts that the requestor stated are not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor suggested that these procedures warrant an O.R. designation because they are placed in an interventional radiology suite or in the operating room under anesthesia. The ten procedure codes are shown in the following table.

ICD-10-PCS Code	Code Description
0JH63XZ	Insertion of tunneled vascular access device into chest subcutaneous tissue and fascia, percutaneous approach
0JH83XZ	Insertion of tunneled vascular access device into abdomen subcutaneous tissue and fascia, percutaneous approach
0JHD3XZ	Insertion of tunneled vascular access device into right upper arm subcutaneous tissue and fascia, percutaneous approach
0JHF3XZ	Insertion of tunneled vascular access device into left upper arm subcutaneous tissue and fascia, percutaneous approach
0JHG3XZ	Insertion of tunneled vascular access device into right lower arm subcutaneous tissue and fascia, percutaneous approach
0JHH3XZ	Insertion of tunneled vascular access device into left lower arm subcutaneous tissue and fascia, percutaneous approach
0JHL3XZ	Insertion of tunneled vascular access device into right upper leg subcutaneous tissue and fascia, percutaneous approach
0JHM3XZ	Insertion of tunneled vascular access device into left upper leg subcutaneous tissue and fascia, percutaneous approach
0JHN3XZ	Insertion of tunneled vascular access device into right lower leg subcutaneous tissue and fascia, percutaneous approach
0JHP3XZ	Insertion of tunneled vascular access device into left lower leg subcutaneous tissue and fascia, percutaneous approach

According to the requestor, it does not make sense for tunneled vascular access devices to group to procedural MS–DRGs in limited circumstances as is the case currently with the logic in MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). The requestor stated that these procedures should be grouping to procedural MS–DRGs across all MDCs.

We note that we have addressed requests related to these procedures in previous rulemaking (85 FR 58511 through 58517). Our clinical advisors reviewed this request and disagree that procedures performed to insert a tunneled vascular access device should group to procedural MS–DRGs across all MDCs. They stated that these percutaneous procedures are generally performed in the outpatient setting and when performed during a hospitalization, they are frequently performed in combination with another O.R. procedure. Therefore, we are proposing to maintain the current non-O.R. status for the ten procedure codes listed previously for FY 2022.

12. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2022

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because

of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16- (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

We discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554) that we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of our response to public comments regarding the nine guiding principles. We continue to solicit feedback regarding these guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

For new diagnosis codes approved for FY 2022, consistent with our annual process for designating a severity level (MCC, CC or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to II.D.13 of this proposed rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2022.

For this FY 2022 IPPS/LTCH PPS proposed rule, we received several requests to change the severity level designations of specific ICD–10–CM diagnosis codes. Our clinical advisors believe it is appropriate to consider these requests in connection with our continued comprehensive CC/MCC analysis in future rulemaking, rather than proposing to change the designation of individual ICD–10–CM diagnosis codes at this time. As stated earlier in this section, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We will consider these individual requests received for changes to severity level designations as we continue our comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

c. Potential Change to Severity Level Designation for Unspecified Diagnosis Codes for FY 2022

For this FY 2022 IPPS/LTCH PPS proposed rule, as another interval step as we continue to address the comprehensive review of the severity designations of ICD–10–CM diagnosis codes in which we have been engaged over the past two years, we are requesting public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we are considering adopting for FY 2022.

Specifically, we are considering changing the severity level designation of all ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site, effective for FY 2022, after consideration of the public comments we receive in response to this proposed rule.

According to the ICD–10–CM Official Guidelines for Coding and Reporting, codes titled ''unspecified'' are for use when the information in the medical record is insufficient to assign a more specific code. In our review of severity level designation of the codes in the ICD–10–CM classification, we noted 3,490 ''unspecified'' diagnosis codes designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site with an equivalent severity level designation. For example, ICD–10–CM code L89.003 (Pressure ulcer of unspecified elbow, stage 3) is currently designated as a MCC. In the same code subcategory of L89.0- (Pressure ulcer of elbow), ICD–10–CM codes L89.013 (Pressure ulcer of right elbow, stage 3) and code L89.023 (Pressure ulcer of left elbow, stage 3) are also designed as MCCs.

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described the categorization of diagnoses as an MCC, a CC, or a NonCC, accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. As such, the designation of CC or MCC is intended to account for the increased resources required to address a condition as a secondary diagnosis. The usage of ''unspecified'' diagnosis codes where there are other codes available in that code subcategory that further specify the anatomic site may contribute to and eventually result in less reliable data for researching clinical outcomes. If documentation is not available to code to the highest level of specificity as to the laterality of the condition treated, and an unspecified code is reported by the hospital, it may be harder to quantify in the claims data what additional resources were expended to address that condition in terms of requiring clinical evaluation, therapeutic treatment, diagnostic procedures, extended length of hospital stay, increased nursing care and/or monitoring.

As stated previously, we discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554) that we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data, and the application of nine guiding principles, and plan to present the findings and proposals in future rulemaking. As patients present with a variety of diagnoses, in examining the secondary diagnoses, we stated we would consider what additional resources are required, that surpasses those that are already being utilized to address the principal diagnosis and/or other secondary diagnoses that might also be present on the claim. The goal of our comprehensive analysis is to create stratification for reimbursing inpatient hospitalization in the fewest amount of categories with the most explanatory power in a clinically cohesive way. We believe more robust claims data would facilitate this effort to determine the impact on resource use and inform our decision-making in determining the most appropriate CC subclass (NonCC, CC, or MCC) assignment for each diagnosis as a secondary diagnosis. As part of this effort, we are soliciting comments on adopting a change to the severity level designation of the 3,490 ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a NonCC for FY 2022.

As discussed in the HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS proposed rule (73 FR 49796 through 49803), in proposing the adoption of ICD–10–CM and ICD–10–PCS, we listed that the addition of laterality in ICD–10–CM— specifying which organ or part of the body is involved when the location could be on the right, the left, or could be bilateral, was one of several improvements over ICD–9–CM. We also noted that in comparison to ICD–9–CM, ICD–10–CM diagnosis codes are very specific and that this specificity improves the richness of data for analysis and improves the accuracy of data used for medical research. In the Modifications to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS final rule (74 FR 3328 through 3362), we adopted the ICD–10–CM and ICD–10–PCS as medical data code sets under HIPAA, replacing ICD–9–CM Volumes 1 and 2, and Volume 3 and noted that ICD–10–CM and ICD–10–PCS provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes. We continue to believe that reporting the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition would more accurately reflect the health care encounter and improve the reliability and validity of the coded data.

We believe that changing the severity level for these ''unspecified codes'' as compared to the more specific codes in the same subcategory recognizing laterality would leverage the additional specificity available under the ICD–10 system, by fostering the reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data. However in consideration of the PHE, and to the extent that some providers may not currently have programs in place that focus on improving documentation, we are requesting public comments on making this change to the severity level designation for these unspecified ICD–10–CM diagnosis codes for FY 2022.

The diagnosis codes for which we are soliciting comments on a change in severity level designation as described in this proposed rule are shown in Table 6P.2a (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*). We note we are also making available the data describing the impact on resource use when reported as a secondary diagnosis for all 3,490 ICD–10–CM unspecified diagnosis codes. While these claims data were not used in our identification of the ''unspecified'' diagnosis codes for which there are other codes available in the code subcategory that further specify the anatomic site, as mentioned earlier in this section, these data are consistent with data historically used to mathematically measure impact on resource use for secondary diagnoses, and the data which we plan to use in combination with application of the nine guiding principles as we continue a comprehensive CC/MCC analysis. Therefore, we are displaying the data on these unspecified codes in order to facilitate public comment on these potential changes in the severity level designation for these codes.

In Table 6P.2a associated with this proposed rule, column C displays the FY 2020 severity level designation for these diagnosis codes in MS–DRG Grouper Version 37.2. Column D displays CMS' current FY 2021 severity level designation in MS–DRG Grouper

Version 38.1 and column E displays the potential changes to the severity level designation that we are considering adopting. Columns F–O show data on the impact on resource use generated using discharge claims from the September 2019 update of the FY 2019 MedPAR file and MS–DRG Grouper Version 37.2. Columns Q–Z show data on the impact on resource use generated using discharge claims from the September 2020 update of the FY 2020 MedPAR file and MS–DRG Grouper Version 38.1.

For further information on the data on the impact on resource use as displayed in Columns F–O and Columns Q–Z, we refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of the methodology utilized to mathematically measure the impact on resource use. Also, as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the data describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

This table shows the Version 38.1 ICD–10 MS–DRG categorization of diagnosis codes by severity level.

Current Categorization of CC Codes (Version 38.1)	
	Number of Codes
MCC	3,278
CC	14,679
NonCC	54,664
Total	72,621

We are requesting public comments on a modification to the Version 38.1 severity level subclass assignments for 4.8 percent of the ICD–10–CM diagnosis codes, potentially effective with the Version 39 ICD–10 MS–DRG MCC/CC list. The following table compares the Version 38.1 ICD–10 MS–DRG MCC/CC list and the potential Version 39 ICD–10 MS–DRG MCC/CC list. There are 17,957 diagnosis codes on the Version 38.1 MCC/CC lists. These potential MCC/CC severity level changes would reduce the number of diagnosis codes on the MCC/CC lists to 14,467 (2,771+ 11,696).

POTENTIAL MCC/CC SUBCLASS MODIFICATIONS						
Severity Level – CC Subclass	**Version 38.1 Severity Level Number of Codes**	**Potential Version 39 Severity Level Number of Codes**	**Percent Change**	**Potential Version 39 Change to MCC subclass, Number of Codes**	**Potential Version 39 Change to CC subclass, Number of Codes**	**Potential Version 39 Change to NonCC subclass, Number of Codes**
MCC	3,278	2,771	-15.5%	N/A	0	507
CC	14,679	11,696	-20.3	0	N/A	2,983
NonCC	54,664	58,154	6.4%	0	0	N/A
Total	**72,621**	**72,621**	**N/A**	**0**	**0**	**3,490**

The net result of these potential changes to the Version 39 ICD–10 MS–DRG MCC/CC list, for the 72,621 diagnosis codes in the ICD–10–CM classification, would be a decrease of 507 (3,278 − 2,771) codes designated as an MCC, a decrease of 2,983 (14,679 − 11,696) codes designated as a CC, and an increase of 3,490 (58,154 − 54,664) codes designated as a NonCC.

The following table compares the Version 38.1 ICD–10 MS–DRG severity level list and the potential Version 39 ICD–10 MS–DRG severity level list by each of the 22 chapters of the ICD–10–CM classification to display how each chapter of ICD–10–CM might be affected by these modifications.

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ICD-10-CM Chapter	Version 38.1 MCC+CC Subclass, Number of Codes	Potential Version 39 Change to NonCC subclass, Number of Codes	Potential Version 39 Severity Level Number of Codes	Percent Change
Certain infectious and parasitic diseases (A00-B99)	757	0	757	0%
Neoplasms (C00-D49)	782	31	751	-4.0%
Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism (D50-D89)	142	0	142	0%
Endocrine, nutritional and metabolic diseases (E00-E89)	246	0	246	0%
Mental, Behavioral and Neurodevelopmental disorders (F01-F99)	265	0	265	0%
Diseases of the nervous system (G00-G99)	250	6	244	-2.4%
Diseases of the eye and adnexa (H00-H59)	259	62	197	-23.9%
Diseases of the ear and mastoid process (H60-H95)	32	5	27	-15.6%
Diseases of the circulatory system (I00-I99)	709	58	651	-8.2%
Diseases of the respiratory system (J00-J99)	160	0	160	0%

Diseases of the digestive system (K00-K95)	397	0	397	0%
Diseases of the skin and subcutaneous tissue (L00-L99)	323	55	268	-17.0%
Diseases of the musculoskeletal system and connective tissue (M00-M99)	1,414	413	1,001	-29.2%
Diseases of the genitourinary system (N00-N99)	168	2	166	-1.2%
Pregnancy, childbirth and the puerperium (O00-O9A)	652	4	648	-0.6%
Certain conditions originating in the perinatal period (P00-P96)	163	0	163	0%
Congenital malformations, deformations and chromosomal abnormalities (Q00-Q99)	252	0	252	0%
Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified (R00-R99)	74	0	74	0%
Injury, poisoning and certain other consequences of external causes (S00-T88)	10,867	2,854	8,013	-26.3%
External causes of morbidity (V00-Y99)	0	0	0	0%
Factors influencing health status and contact with health services (Z00-Z99)	44	0	44	0%
Codes for special purposes (U00-U85)	1	0	1	0%
Total	**17,957**	**3,490**	**14,467**	**-19.4%**

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As shown in the table, the Diseases of the Musculoskeletal System and Connective Tissue (M00–M99) chapter of ICD–10–CM would have the largest percentage reduction in codes designated as CC/MCC. Twelve chapters would have a zero percentage change to the percentage of codes designated as CC/MCC.

As stated previously, we are requesting public comments on our possible adoption of a change to the severity level designation of these 3,490 ''unspecified'' diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to a NonCC, potentially effective with the Version 39 ICD–10 MS–DRG MCC/CC list. As part of this request, we would be interested in comments regarding whether this modification might present operational challenges and how we might otherwise foster the reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately

reflect each health care encounter and improve the reliability and validity of the coded data.

d. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2022

The following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions to the diagnosis code CC severity levels list for FY 2022 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

Table 6I.1—Proposed Additions to the MCC List—FY2022;

Table 6I.2— Proposed Deletions to the MCC List—FY2022; and

Table 6J.1— Proposed Additions to the CC List—FY2022.

e. Proposed CC Exclusions List for FY 2022

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 38.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

As discussed in section II.D.12.c. of the preamble of this proposed rule, we are requesting public comments on potential changes to the severity level for 3,490 diagnosis codes describing an ''unspecified'' anatomic site, from a CC severity level to a NonCC severity level, for FY 2022. We refer the reader to Table 6P.3a associated with this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html)* for the list of the 3,490 diagnosis codes that are currently listed in Part 1 of the CC Exclusions List and are defined as a CC when reported as a secondary diagnosis. Table 6P.3a is divided into several tabs, with the first tab titled ''SDX Codes and Exclu Categories'' containing columns A, B, and C. Column A (titled ''ICD–10–CM Code'') lists the ''unspecified'' diagnosis codes that are currently listed in Part 1 of Appendix C of the CC Exclusions List, column B (titled ''Description'') lists the narrative description of each diagnosis code, and column C (titled Exclusion Category) contains a hyperlink to the collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC diagnosis to be considered as a NonCC. For example, for line 2, Column A displays diagnosis code C34.00, column B displays ''Malignant neoplasm of unspecified main bronchus'' and column C displays a hyperlink to Exclusion Category number 280. When the user clicks on the hyperlink for number 280, they are directed to another tab labeled ''PDX Category 280'' that contains the list of diagnosis codes which, when reported as the principal diagnosis, would cause the corresponding CC diagnosis to be considered as a NonCC. In connection with the request for public comments on the potential changes to the severity level for 3,490 diagnosis codes describing an ''unspecified'' anatomic site, from a CC severity level to a NonCC severity level for FY 2022, Table 6P.3a is being made available for readers to review and consider the list of the 3,490 ''unspecified'' diagnosis codes that are currently included in Part 1 of the CC Exclusions List and the principal diagnosis exclusion category with which they are currently associated. If we were to finalize the potential changes to the severity level for the 3,490 diagnosis codes describing an ''unspecified'' anatomic site from a CC severity level to a NonCC severity level for FY 2022, we would also finalize the removal of these codes from the CC Exclusions List for FY 2022.

We received three requests related to the CC Exclusions List logic, as we discuss in this section of this proposed rule.

We received a request to review the secondary diagnoses that are excluded as a CC or MCC in the CC Exclusions List logic when any one of the following three diagnosis codes is reported as the principal diagnosis.

ICD-10-CM Code	Code Description
O99.891	Other specified diseases and conditions complicating pregnancy
O99.892	Other specified diseases and conditions complicating childbirth
O99.893	Other specified diseases and conditions complicating puerperium

According to the requestor, in the ICD–10 MS–DRGs version 37.2 CC Exclusions List logic, the predecessor code for the listed diagnosis codes, diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) is listed in the collection of principal diagnosis list number 1000, therefore, when a CC or MCC secondary diagnosis associated with that principal diagnosis list describes a condition as occurring in pregnancy, childbirth or the puerperium, the CC Exclusions List logic will render that diagnosis code as a NonCC. The requestor stated that because diagnosis code O99.89 under version 37.2 of the ICD–10 MS–DRGs is now a subcategory under version 38.1 of the ICD–10 MS–DRGs, with three unique diagnosis codes to specify which obstetric stage the patient is in, that further analysis of the new diagnosis codes (O99.891, O99.892, and O99.893) should occur to determine if changes to the collection of principal diagnosis list is warranted. The requestor provided three examples for CMS to review and consider for possible changes to the CC Exclusions List logic.

In the first example, the requestor noted that diagnosis code O72.1 (Other immediate postpartum hemorrhage) is listed as a CC secondary diagnosis associated with the collection of principal diagnosis list number 1000, and that under the ICD–10 MS–DRGs version 38.1 CC Exclusions List logic, the diagnosis listed in principal diagnosis collection 1000 is now diagnosis code O99.893 (Other specified diseases and conditions complicating puerperium). Thus, both diagnosis codes (O72.1 and O99.893) are describing conditions occurring specifically in the postpartum or puerperium period. The postpartum period is defined as the period beginning immediately after delivery and continues for six weeks following delivery. A postpartum complication is any complication occurring within the six-week period. The requestor stated that because diagnosis code O72.1 is assigned for documented postpartum uterine atony with hemorrhage when it occurs immediately following the delivery of the baby and placenta, that CMS should review diagnosis code O99.892 (Other specified diseases and conditions complicating childbirth) and determine if it should be added to the collection of principal diagnosis list number 1000 to cause diagnosis code O72.1 to be considered as a NonCC when diagnosis code O99.892 is reported as the principal diagnosis.

In the second example, the requestor noted that diagnosis code O98.32 (Other infections with a predominantly sexual mode of transmission complicating childbirth) is associated with principal diagnosis collection number 1012. The requestor also noted that principal diagnosis collection number 1012 does not list diagnosis codes O99.891, O99.892, or O99.893 as a principal diagnosis to exclude the CC secondary diagnosis code O98.32, however, it does list diagnosis codes O98.311 (Other infections with a predominantly sexual mode of transmission complicating pregnancy, first trimester), O98.312 (Other infections with a predominantly sexual mode of transmission complicating pregnancy, second trimester), and O98.313 (Other infections with a predominantly sexual mode of transmission complicating pregnancy, third trimester) as a principal diagnosis to exclude the CC secondary diagnosis code O98.32. The requestor recommended CMS review diagnosis codes O98.32 (Other infections with a predominantly sexual mode of transmission complicating childbirth) and O98.33 (Other infections with a predominantly sexual mode of transmission complicating the puerperium), to determine if diagnosis codes O99.891, O99.892 or O99.893, when reported as a principal diagnosis, should exclude CC secondary diagnosis codes O98.32 and O98.33. Thus, the requestor suggested CMS consider if it is appropriate to add diagnosis codes O99.891, O99.892 and O99.893 to principal diagnosis collection number 1012 to cause diagnosis code O98.32 to be considered as a NonCC when diagnosis codes O99.891, O99.892 or O99.893 are reported as the principal diagnosis.

In the third example, the requestor noted that diagnosis code O87.2 (Hemorrhoids in the puerperium) is associated with principal diagnosis collection number 4041. The requestor also noted that principal diagnosis collection number 4041 lists diagnosis code O99.893 as a principal diagnosis to exclude the CC diagnosis code O87.2, however, it does not list diagnosis code O99.892. The requestor further noted that the ''Includes'' note at Category O87 (Venous complications and hemorrhoids in the puerperium) in the FY 2021 ICD–10–CM Tabular List includes ''venous complications in labor, delivery and the puerperium'', therefore, diagnosis code O87.2 would also be reported for documented hemorrhoids during labor and delivery. The requestor recommended CMS review diagnosis code O99.892 to determine if, when reported as a principal diagnosis, it should exclude CC diagnosis code O87.2. Thus, the requestor suggested CMS consider if it is appropriate to add diagnosis code O99.892 to principal diagnosis collection number 4041 to cause diagnosis code O87.2 to be considered as a NonCC when diagnosis code O99.892 is reported as the principal diagnosis.

We reviewed diagnosis codes O99.891, O99.892 and O99.893 with respect to the principal diagnosis collection list and because these diagnosis codes are specifically describing ''other specified diseases and conditions complicating pregnancy, childbirth, and the puerperium,'' respectively, we do not believe that any of these three diagnosis codes, when reported as a principal diagnosis, should exclude any CC secondary diagnosis. In cases where any one of these three diagnosis codes is reported as a principal diagnosis, which are generally anticipated to be rare, it is understood that there is not a more specific diagnosis code available in the classification to report as the principal diagnosis that identifies the underlying or associated cause of the disease or the condition complicating the specific obstetric stage (pregnancy, childbirth, or puerperium), hence the ''other specified'' in the code title. Specifically, the title of category O99 is ''Other maternal diseases classifiable elsewhere but complicating pregnancy, childbirth and the puerperium'' and there are nine subcategories, each of which is generally associated with a single organ

system or etiology, with the exception of the ''other specified'' subcategory (O99.8) as displayed in the following table.

Subcategories within ICD-10-CM Category O99 Other Maternal Diseases Classifiable Elsewhere But Complicating Pregnancy, Childbirth and the Puerperium	
Subcategory	**Description**
O99.0	Anemia complicating pregnancy, childbirth, and the puerperium
O99.1	Other diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism complicating pregnancy, childbirth and the puerperium
O99.2	Endocrine, nutritional and metabolic diseases complicating pregnancy, childbirth and the puerperium
O99.3	Mental disorders in diseases of the nervous system complicating pregnancy, childbirth and the puerperium
O99.4	Diseases of the circulatory system complicating pregnancy, childbirth and the puerperium
O99.5	Diseases of the respiratory system complicating pregnancy, childbirth and the puerperium
O99.6	Diseases of the digestive system complicating pregnancy, childbirth and the puerperium
O99.7	Diseases of the skin and subcutaneous tissue complicating pregnancy, childbirth and the puerperium
O99.8	Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium

The instructional note at category O99 states ''use additional code to identify specific condition'' and included at each subcategory (O99.0–O99.7) are a range of codes that refer to diagnoses that are associated with the condition in the title of the subcategory that are to be reported in addition to the applicable code within the respective subcategory. For example, at subcategory O99.0 (Anemia complicating pregnancy, childbirth, and the puerperium), the range of associated codes to identify the specific condition (for example, type of anemia) includes conditions in diagnosis code range D50–D64, meaning that when any one of the diagnosis codes under subcategory O99.0 describing anemia complicating a specific obstetric stage (pregnancy, childbirth, or puerperium) is reported, a code within the D50–D64 code range to identify the specific type of anemia would also be expected to be reported when supported by the medical record documentation. It is therefore reasonable to associate the two conditions (one from subcategory O99.0 and one from code range D50–D64) when reported on a claim. However, the same cannot be stated for subcategory O99.8. There is no range of associated codes from which users are instructed to report located at this particular subcategory in addition to the specific code under sub-subcategory O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium). We note that subcategory O99.8 and sub-subcategory O99.89 have the same title. Therefore, when a diagnosis code from other than that sub-subcategory is reported that describes a condition occurring in any one of the obstetric stages (pregnancy, childbirth, or puerperium) it is not clear if the condition can reasonably be associated to correspond to the ''other specified diseases and conditions'' diagnosis. In addition, the code ranges included at subcategory O99.8 are D00–D48, H00–H95, M00–N99, and Q00–Q99. Consequently, diagnosis codes within those code ranges would be expected to be reported with one of the diagnosis codes under subcategory O99.8 when reported as a principal diagnosis.

In all three of the requestor's examples, the diagnosis codes provided for CMS to review and consider are located in the ''O'' code range (O72.1, O98.32, and O87.2 in addition to O99.891, O99.892, and O99.893). As noted previously, the code ranges included at subcategory O99.8 as listed, do not include any codes in ''O'' code range. Upon review of the diagnosis codes provided by the requestor, it is also reasonable to expect that any one of those diagnosis codes (O72.1, O98.32, and O87.2) could be reported as a principal diagnosis alone. For instance, there are no instructional notes at diagnosis code O72.1 that preclude that diagnosis code from being reported as the principal diagnosis.

During our review of the CC Exclusions List logic in response to the requestor's recommendations, we also identified some diagnosis codes describing the specific trimester of pregnancy that we believe warrant further examination. We are unable to fully evaluate these conditions for FY 2022, therefore, we will continue to analyze for future rulemaking.

For the reasons discussed, we do not believe that any of the three diagnosis codes (O99.891, O99.892, and O99.893), when reported as a principal diagnosis, should exclude any CC secondary diagnosis. Therefore, we are proposing to remove diagnosis codes O99.891, O99.892, and O99.893 from the CC Exclusions List logic principal diagnosis collection lists. Specifically, we are proposing to remove those diagnosis codes from the following principal

diagnosis collection list numbers 0085, 0954, 0956 through 0963, 0972, 0988, 0991 through 0998, 1000 through 1002, 1004, 1006, 1009, 1011, 1014, 1015, 1019, 3999, 4000, 4002 through 4006, 4008, 4010, through 4013, 4017, 4020, 4021, 4023 through 4026, 4030, 4031, 4033 through 4043, 4050 through 4054, 4059 through 4063, 4065 and 4067, effective FY 2022.

We also received a request to review diagnosis codes describing oxygen dependence, chronic obstructive pulmonary disease with exacerbation, and chronic respiratory failure with regard to assignment in MS–DRG 191 (Chronic Obstructive Pulmonary Disease with CC) and to consider whether any changes to principal diagnosis collection number 0744 in the CC Exclusions List logic are warranted.

The requestor provided diagnosis codes J44.1 (Chronic obstructive pulmonary disease with (acute) exacerbation), J96.11 (Chronic respiratory failure with hypoxia (CC)) and Z99.81 (Dependence on supplemental oxygen) for CMS to review. Specifically, the requestor suggested that if oxygen dependence, by definition, is clinically inherent to chronic respiratory failure, then CMS should consider adding diagnosis code J44.1 to the CC Exclusions List logic principal diagnosis collection list number 0744 and cause diagnosis code J96.11 to be considered as a NonCC when J44.1 is reported as the principal diagnosis.

We reviewed the diagnosis codes and MS–DRG assignment as the requestor suggested. We confirmed that when diagnosis code J44.1 is reported as the principal diagnosis with the CC secondary diagnosis code J96.11, and secondary diagnosis code Z99.81, the resulting MS–DRG assignment is MS–DRG 191. We believe that diagnosis code J96.11 should continue to group as a CC, to the ''with CC'' MS–DRG 191, when reported as a secondary diagnosis code with diagnosis code J44.1 reported as the principal diagnosis. We disagree with the requestor's suggestion that every oxygen-dependent COPD patient has chronic respiratory failure, and that separately reporting the chronic respiratory failure is clinically redundant. Patients can be oxygen-dependent with COPD and not have a diagnosis of chronic respiratory failure. Therefore, we are proposing to maintain the structure of principal diagnosis collection list number 0744 in the CC Exclusions List logic for FY 2022.

Finally, we received a request to reconsider the MCC exclusions for diagnosis code I11.0 (Hypertensive heart disease with heart failure) when reported as the principal diagnosis. According to the requestor, there appears to be an inconsistency for the CC Exclusions List logic. Specifically, the requestor noted that when diagnosis code I11.0 is reported as the principal diagnosis, it causes the following MCC secondary diagnosis codes to be considered as a NonCC.

ICD-10-CM Code	Code Description
I50.23	Acute on chronic systolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure

However, the requestor stated that diagnosis codes I50.21 (Acute systolic (congestive) heart failure) and I50.31 (Acute diastolic (congestive) heart failure) are not excluded from acting as MCCs when diagnosis code I11.0 is reported as the principal diagnosis. The requestor also stated that all diagnosis codes in category I50 (Heart Failure) share common etiologies and demonstrate comparable severity of illness. Therefore, the requestor suggested that none of the conditions in this category (I50) should be excluded from acting as a MCC when diagnosis code I11.0 is reported as a principal diagnosis.

We examined all the diagnosis codes in category I50 with regard to the CC Exclusions List logic. In addition to diagnosis code I11.0, we also reviewed diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease) when reported as a principal diagnosis because that diagnosis code also has the Tabular instruction ''use additional code to identify the type of heart failure''.

We found additional inconsistencies in the CC secondary diagnosis heart failure codes where some diagnoses were excluded depending on the principal diagnosis reported and others were not excluded. As a result, we are proposing to revise the CC Exclusions Logic list for diagnosis codes I11.0 and I13.2 when reported as a principal diagnosis to ensure they are consistent in the CC and MCC diagnoses they exclude. In the following table we show the findings for each diagnosis code in category I50 with respect to the current severity level (MCC, CC or NonCC), if it is currently excluded as a CC or MCC when reported with either diagnosis code I11.0 or I13.2 as the principal diagnosis, and what our proposal is under the CC Exclusions List logic for FY 2022.

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ICD-10-CM Code	Code Description	Principal Diagnosis I11.0	Principal Diagnosis I13.2	Proposal for FY 2022
I50.1 (CC)	Left ventricular failure, unspecified	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.20 (CC)	Unspecified systolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.21 (MCC)	Acute systolic (congestive) heart failure	Not excluded	Not excluded	No change
I50.22 (CC)	Chronic systolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.23 (MCC)	Acute on chronic systolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.30 (CC)	Unspecified diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.31 (MCC)	Acute diastolic (congestive) heart failure	Not excluded	Not excluded	No change
I50.32 (CC)	Chronic diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.33 (MCC)	Acute on chronic diastolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.40 (CC)	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2
I50.41 (MCC)	Acute combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.42 (CC)	Chronic combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Add to CC Exclusion List for Principal Dx I13.2

I50.43 (MCC)	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure	Excluded	Not excluded	Remove from CC Exclusion List for Principal Dx I11.0
I50.810 (NonCC)	Right heart failure, unspecified	Not excluded	Not excluded	No change
I50.811 (NonCC)	Acute right heart failure	Not excluded	Not excluded	No change
I50.812 (NonCC)	Chronic right heart failure	Not excluded	Not excluded	No change
I50.813 (NonCC)	Acute on chronic right heart failure	Not excluded	Not excluded	No change
I50.814 (NonCC)	Right heart failure due to left heart failure	Not excluded	Not excluded	No change
I50.82 (NonCC)	Biventricular heart failure	Not excluded	Not excluded	No change
I50.83 (NonCC)	High output heart failure	Not excluded	Not excluded	No change
I50.84 (NonCC)	End stage heart failure	Not excluded	Not excluded	No change
I50.89 (NonCC)	Other heart failure	Not excluded	Not excluded	No change
I50.9 (NonCC)	Heart failure, unspecified	Not excluded	Not excluded	No change

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We are proposing additional changes to the ICD–10 MS–DRGs Version 39 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.D.13. of this FY 2022 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2022; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2022; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2022; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2022. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this proposed rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

13. Proposed Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2022, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes and Table 6E.—Revised Diagnosis Code Titles for this proposed rule.

These tables are not published in the Addendum to this proposed rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. As discussed in section II.D.16. of the preamble of this proposed rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this proposed rule:

- Table 6A.—New Diagnosis Codes—FY 2022;
- Table 6B.—New Procedure Codes—FY 2022;
- Table 6C.—Invalid Diagnosis Codes—FY 2022;
- Table 6D.—Invalid Procedure Codes—FY 2022;
- Table 6E.—Revised Diagnosis Code Titles—FY 2022;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2022;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2022;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2022;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2022;
- Table 6I.1.—Proposed Additions to the MCC List—FY 2022;
- Table 6I.2.—Proposed Deletions to the MCC List—FY 2022; and
- Table 6J.1.—Proposed Additions to the CC List—FY 2022.

14. Proposed Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we made available the FY 2021 ICD–10 MCE Version 38 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 38 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

For this FY 2022 IPPS/LTCH PPS proposed rule, we address the MCE requests we received by the November 1, 2020 deadline. We also discuss the proposals we are making based on our internal review and analysis.

a. External Causes of Morbidity Codes as Principal Diagnosis

In the MCE, the external cause codes (V, W, X, or Y codes) describe the circumstance causing an injury, not the nature of the injury, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We are proposing to add the following new ICD–10–CM diagnosis codes to the External Causes of Morbidity edit code list.

ICD-10-CM code	Code description
Y35.899A	Legal intervention involving other specified means, unspecified person injured, initial encounter
Y35.899D	Legal intervention involving other specified means, unspecified person injured, subsequent encounter
Y35.899S	Legal intervention involving other specified means, unspecified person injured, sequela

b. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Pediatric Diagnoses

Under the ICD–10 MCE, the Pediatric diagnoses category for the Age conflict edit considers the age range of 0 to 17 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We are proposing to add the following new ICD–10–CM diagnosis codes to the Pediatric diagnoses category code list under the Age conflict edit.

ICD-10-CM code	Code description
R63.31	Pediatric feeding disorder, acute
R63.32	Pediatric feeding disorder, chronic

c. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Females Only Edit

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. We are proposing to add the following new ICD–10–CM diagnosis codes to the edit code list for the Diagnoses for Females Only edit.

ICD-10-CM code	Code description
C56.3	Malignant neoplasm of bilateral ovaries
C79.63	Secondary malignant neoplasm of bilateral ovaries

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in Section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2021. In addition, as a result of proposed new instructional notes to ''Code first underlying disease'' (which indicate the proper sequencing order of the codes) for existing diagnosis codes found at subcategory M40.1 (Other secondary kyphosis) and subcategory M41.5 (Other secondary scoliosis) discussed at the September 8–9, 2020 ICD–10 Coordination and Maintenance Committee meeting, we are proposing to add the following new and, if these instructional notes are finalized, existing ICD–10–CM diagnosis codes at subcategories M40.1 and M41.5, to the Unacceptable Principal Diagnosis edit code list.

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ICD-10-CM code	Code description
G92.00	Immune effector cell-associated neurotoxicity syndrome, grade unspecified
G92.01	Immune effector cell-associated neurotoxicity syndrome, grade 1
G92.02	Immune effector cell-associated neurotoxicity syndrome, grade 2
G92.03	Immune effector cell-associated neurotoxicity syndrome, grade 3
G92.04	Immune effector cell-associated neurotoxicity syndrome, grade 4
G92.05	Immune effector cell-associated neurotoxicity syndrome, grade 5
M40.10	Other secondary kyphosis, site unspecified
M40.12	Other secondary kyphosis, cervical region
M40.13	Other secondary kyphosis, cervicothoracic region
M40.14	Other secondary kyphosis, thoracic region
M40.15	Other secondary kyphosis, thoracolumbar region
M41.50	Other secondary scoliosis, site unspecified
M41.52	Other secondary scoliosis, cervical region
M41.53	Other secondary scoliosis, cervicothoracic region
M41.54	Other secondary scoliosis, thoracic region
M41.55	Other secondary scoliosis, thoracolumbar region
M41.56	Other secondary scoliosis, lumbar region
M41.57	Other secondary scoliosis, lumbosacral region
R0.54	Cough syncope
S06.A0XA	Traumatic brain compression without herniation, initial encounter
S06.A0XD	Traumatic brain compression without herniation, subsequent encounter
S06.A0XS	Traumatic brain compression without herniation, sequela
S06.A1XA	Traumatic brain compression with herniation, initial encounter
S06.A1XD	Traumatic brain compression with herniation, subsequent encounter
S06.A1XS	Traumatic brain compression with herniation, sequela
T40.715A	Adverse effect of cannabis, initial encounter
T40.715D	Adverse effect of cannabis, subsequent encounter
T40.715S	Adverse effect of cannabis, sequela
T40.716A	Underdosing of cannabis, initial encounter
T40.716D	Underdosing of cannabis, subsequent encounter
T40.716S	Underdosing of cannabis, sequela
T40.725A	Adverse effect of synthetic cannabinoids, initial encounter
T40.725D	Adverse effect of synthetic cannabinoids, subsequent encounter
T40.725S	Adverse effect of synthetic cannabinoids, sequela
T40.726A	Underdosing of synthetic cannabinoids, initial encounter
T40.726D	Underdosing of synthetic cannabinoids, subsequent encounter
T40.726S	Underdosing of synthetic cannabinoids, sequela
Z71.85	Encounter for immunization safety counseling
Z91.014	Allergy to mammalian meats
Z91.51	Personal history of suicidal behavior
Z91.52	Personal history of nonsuicidal self-harm
Z92.850	Personal history of Chimeric Antigen Receptor T-cell therapy
Z92.858	Personal history of other cellular therapy
Z92.859	Personal history of cellular therapy, unspecified
Z92.86	Personal history of gene therapy

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In addition, as discussed in section II.D.13. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are

no longer effective October 1, 2021. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the Unacceptable Principal Diagnosis edit code list. We are proposing to delete these codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM code	Code description
T40.7X5A	Adverse effect of cannabis (derivatives), initial encounter
T40.7X5D	Adverse effect of cannabis (derivatives), subsequent encounter
T40.7X5S	Adverse effect of cannabis (derivatives), sequela
T40.7X6A	Underdosing of cannabis (derivatives), initial encounter
T40.7X6D	Underdosing of cannabis (derivatives), subsequent encounter
T40.7X6S	Underdosing of cannabis (derivatives), sequela
Z91.5	Personal history of self-harm

e. Unspecified Codes

As discussed in section II.D.12.c. of the preamble of this proposed rule, we are requesting public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we are considering adopting for FY 2022. In connection with that request, we are also requesting public comments on the potential creation of a new MCE code edit involving these ''unspecified'' codes for FY 2022. Specifically, this MCE code edit could trigger when an ''unspecified'' diagnosis code currently designated as either a CC or MCC, that includes other codes available in that code subcategory that further specify the anatomic site, is entered. We refer the reader to table 6P.3a (which is available via the internet on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) for the list of unspecified diagnosis codes that would be subject to this edit. This edit could signal to the provider that a more specific code is available to report. We believe this edit aligns with documentation improvement efforts and leverages the specificity within ICD–10. As part of our request for comment on the potential creation of this new MCE code edit for these ''unspecified'' codes, we are interested in comments on how this MCE code edit may be developed for FY 2022 to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

f. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054) we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment and analysis aspects. Subsequently, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235) we stated that we engaged a contractor to assist in the review of the limited coverage and non-covered procedure edits in the MCE that may also be present in other claims processing systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what is already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE.

We have also noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2021.

15. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005

are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

For this FY 2022 IPPS/LTCH PPS proposed rule, we received a request to examine the MS–DRG hierarchy within MDC 05 (Diseases and Disorders of the Circulatory System). The requestor stated its request to review the hierarchy within MDC 05 was based on the relative weights within each MS–DRG subdivision which they stated are supportive of higher position within the hierarchy. The requestor stated that when multiple procedures are performed, it is reasonable for providers to be compensated for the highest weighted procedure. The requestor did not specify which data year it analyzed to identify the relative weights. As discussed in this section, in reviewing the surgical hierarchy, we weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG), not the relative weights of each MS–DRG as suggested by the requestor, to determine average resource consumption for the surgical class; therefore, consistent with our annual process, we used the methodology as described previously to review the surgical hierarchy within MDC 05.

Based on our review of the surgical hierarchy within MDC 05 in response to this request, and in response to the request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation as discussed in section II.D.5.e. of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for the MS–DRGs in MDC 05 for FY 2022. Specifically, we are proposing to sequence MS–DRGs 231–236 above MS–DRGs 222–227 and below MS–DRGs 216–221, sequence MS–DRGs 222–227 above MS–DRGs 266–227 and below MS–DRGs 231–236, sequence MS–DRGs 266–267 above MS–DRGs 268–269 and below MS–DRGs 222–227, sequence MS–DRGs 228–229 above MS–DRGs 319–320 and below MS–DRGs 268–269.

Our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 39 is illustrated in the following table.

Proposed Surgical Hierarchy: MDC 05	
215	Other Heart Assist System Implant
216 – 221	Cardiac Valve and Other Major Cardiothoracic Procedures
231 – 236	Coronary Bypass
222 – 227	Cardiac Defibrillator Implant
266 – 267	Endovascular Cardiac Valve Replacement and Supplement Procedures
268 – 269	Aortic and Heart Assist Procedures
228 – 229	Other Cardiothoracic Procedures
319 – 320	Other Endovascular Cardiac Valve Procedures

16. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/*

codes.html. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2022 at a public meeting held on September 8–9, 2020 and finalized the coding changes after consideration of comments received at the meetings and in writing by November 09, 2020.

The Committee held its 2021 meeting on March 9–10, 2021. The deadline for submitting comments on these code proposals was April 9, 2021. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2021 would be included in the October 1, 2021 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this proposed rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, and Table 6E.—Revised Diagnosis Code Titles for this proposed rule, which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 8–9, 2020 meeting and the March 9–10, 2021 meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the discussions relating to diagnosis codes at the September 8–9, 2020 meeting and March 9–10, 2021 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

As a result of the ongoing COVID–19 public health emergency, the CDC implemented six new diagnosis codes describing conditions related to COVID–19 into the ICD–10–CM effective with discharges on and after January 1, 2021. The diagnosis codes are

ICD-10-CM code	Code description
J12.82	Pneumonia due to coronavirus disease 2019
M35.81	Multisystem inflammatory syndrome (MIS)
M35.89	Other specified systemic involvement of connective tissue
Z11.52	Encounter for screening for COVID-19
Z20.822	Contact with and (suspected) exposure to COVID-19
Z86.16	Personal history of COVID-19

We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/icd10cm.htm* for additional details regarding the implementation of these new diagnosis codes.

We provided the MS–DRG assignments for the six diagnosis codes effective with discharges on and after January 1, 2021, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code, and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new

diagnosis code being assigned to the same MS–DRG as the predecessor code. The assignments for the previously listed diagnosis codes are reflected in Table 6A- New Diagnosis Codes (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). As with the other new diagnosis codes and MS–DRG assignments included in Table 6A of this proposed rule, we are soliciting public comments on the most appropriate MDC, MS–DRG, and severity level assignments for these codes for FY 2022, as well as any other options for the GROUPER logic.

In addition, CMS implemented 21 new procedure codes describing the introduction or infusion of therapeutics, including monoclonal antibodies and vaccines for COVID–19 treatment, into the ICD–10–PCS effective with discharges on and after January 01, 2021. The 21 procedure codes listed in this section of this rule are designated as non-O.R. and do not affect any MDC or MS–DRG assignment as shown in the following table

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ICD-10-PCS Code	Description	O.R.	MDC	MS-DRG
XW013H6	Introduction of other new technology monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013K6	Introduction of leronlimab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013S6	Introduction of COVID-19 vaccine dose 1 into subcutaneous tissue, percutaneous approach, new technology group 6	N		

XW013T6	Introduction of COVID-19 vaccine dose 2 into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW013U6	Introduction of COVID-19 vaccine into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW023S6	Introduction of COVID-19 vaccine dose 1 into muscle, percutaneous approach, new technology group 6	N		
XW023T6	Introduction of COVID-19 vaccine dose 2 into muscle, percutaneous approach, new technology group 6	N		
XW023U6	Introduction of COVID-19 vaccine into muscle, percutaneous approach, new technology group 6	N		
XW033E6	Introduction of etesevimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033F6	Introduction of bamlanivimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033G6	Introduction of REGN-COV2 monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033H6	Introduction of other new technology monoclonal antibody into peripheral vein, percutaneous approach, new technology group 6	N		
XW033L6	Introduction of CD24Fc immunomodulator into peripheral vein, percutaneous approach, new technology group 6	N		
XW043E6	Introduction of etesevimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043F6	Introduction of bamlanivimab monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043G6	Introduction of REGN-COV2 monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043H6	Introduction of other new technology monoclonal antibody into central vein, percutaneous approach, new technology group 6	N		
XW043L6	Introduction of CD24Fc immunomodulator into central vein, percutaneous approach, new technology group 6	N		
XW0DXM6	Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6	N		
XW0G7M6	Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6	N		
XW0H7M6	Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6	N		

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The ICD–10 MS–DRG assignment for cases reporting any one of the 21 procedure codes is dependent on the reported principal diagnosis, any secondary diagnoses defined as a CC or MCC, procedures or services performed, age, sex, and discharge status. The 21 procedure codes are reflected in Table 6B—New Procedure Codes (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.)* As with the other new procedure codes and MS–DRG assignments included in Table 6B of this proposed rule, we are soliciting public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for

these codes for FY 2022, as well as any other options for the GROUPER logic.

We note that Change Request (CR) 11895, Transmittal 10654, titled ''Fiscal Year (FY) 2021 Annual Update to the Medicare Code Editor (MCE) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) and Procedure Coding System (ICD–10–PCS)'', was issued on March 12, 2021 (available via the internet on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r10654cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 38.1, effective with discharges on and after January 1, 2021, reflecting the new diagnosis and procedure codes. The updated software, along with the updated ICD–10 MS–DRG V38.1 Definitions Manual and the Definitions of Medicare Code Edits V38.1 manual is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. Historically, this 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor during the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants of the Committee meeting and those reviewing the Committee meeting materials are encouraged to comment on all such requests. There were no code requests approved for an expedited April 1, 2021 implementation at the September 8–9, 2020 Committee meetings. Therefore, there were no new codes implemented April 1, 2021.

At the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting we announced our consideration of an April 1 implementation date for ICD–10–CM diagnosis and ICD–10–PCS procedure code updates, in addition to the current October 1 annual update for ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes. We stated that this April 1 code update would be in addition to the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act for diagnosis or procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. As explained during the March 9–10, 2021 meeting, we believe this additional April 1 implementation date for new codes would allow for earlier recognition of diagnoses, conditions, and illnesses as well as procedures, services, and treatments in the claims data. We also believe this earlier recognition would be beneficial for purposes of reporting, data collection, tracking clinical outcomes, claims processing, surveillance, research, policy decisions and data interoperability. We note, as previously summarized, that in 2005, in connection with the implementation of the current April 1 update for diagnosis or procedure code revisions for purposes of the new technology add-on payment process, stakeholders expressed concerns with an April 1 update, specifically with regard to the time needed to update hospital systems and obtain new code books and coding software. We believe that the advances in technology that have occurred since

that time, including the use of electronic health records (EHRs), electronic coding books, and updated encoder software that are now utilized by the majority of providers, would alleviate those concerns and make a broader April 1 update more feasible today. Consistent with our established process for the existing April 1 update under section 1886(d)(5)(k)(vii) of the Act, if adopted, any new ICD–10 code updates finalized for implementation on the following April 1 would be announced in November of the prior year, which would provide a 4-month timeframe for the public to receive notice about the diagnosis and/or procedure code updates with respect to the codes, code descriptions, code designations (severity level for diagnosis codes or O.R. status for procedure code) and code assignment under the ICD–10 MS–DRGs. As discussed during the March 9–10, 2021 meeting, all April 1 code update files would be made publicly available by February 1, providing a 2-month timeframe for providers to incorporate systems updates. We also do not anticipate any need for code book publishers to issue new code books as a result of an April 1 code update, if adopted. Rather, as was done in the past at the publisher's discretion, supplemental pages containing the code update information were made available and sent to purchasers of the code book products. We further note that historically, coders would hand-write any updates or notes directly into their code books. In addition, with the availability of electronic code book files, we would anticipate any April 1 code updates, if adopted, could be reasonably completed in the allotted timeframe. For these same reasons, we also do not believe a 5-month time period would continue to be needed to update providers' systems to reflect newly approved coding changes. We further note that if an April 1 update were to be adopted, it could be through a phased approach, such that initially, the number and nature of the code updates would be fewer and less comprehensive as compared to the existing October 1 update. For example, it was discussed during the meeting that consideration could first be given to proposals identified as ''Addenda''. For diagnosis codes, the proposed addenda updates typically consist primarily of minor revisions to the Index and Tabular List, such as corrections to typos and changes to instructional notes. For procedure codes, the proposed addenda updates typically consist primarily of minor revisions to the Index and Tables, such as adding or deleting entries to describe a body part or approach value or making changes to the Substance and Device Keys. We would use our established process to implement an April 1 code update, which would include presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. Under our contemplated process, requestors would indicate whether they are submitting their code request for consideration for an April 1 implementation date, if adopted, or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee would make efforts to accommodate the requested implementation date for each request submitted. However, the Committee would determine which requests would be presented for consideration for an April 1 implementation date or an October 1 implementation date. We refer the reader to the Agenda packet from the meeting at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional information regarding this announcement and our request for comments.

If this new April 1 implementation date is adopted, we would assign the codes approved for the April 1 update to an MS–DRG(s) using our established process for GROUPER assignments for new diagnosis and procedure codes. Specifically, consistent with our established process for assigning new diagnosis and procedure codes, we would review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we would consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process would not automatically result in the new diagnosis or procedure code being assigned to the same MS–DRG or having the same designation as the predecessor code.

ICD–9–CM addendum and code title information is published on the CMS website at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*. CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at: *https://www.cdc.gov/nchs/icd/icd10cm.htm.*

Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the *Coding Clinic for ICD–10.* The AHA also distributes coding update information to publishers and software vendors.

For FY 2021, there are currently 72,621 diagnosis codes and 78,136 ICD–10–PCS procedure codes. As displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with this proposed rule (and available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/,* there are 147 new diagnosis codes and 106 new procedure codes that have been finalized for FY 2022 at the time of the development of this proposed rule. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules. We will continue to provide the October updates in this manner in the IPPS proposed and final rules.

17. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2022

For FY 2022 we are proposing not to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We are proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

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MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC

MDC	MS-DRG	MS-DRG Title
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement And Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	551	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	552	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

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The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY 2022 IPPS/LTCH PPS final rule and also will be issued to providers in the form of a Change Request (CR).

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

E. Recalibration of the FY 2022 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

In accordance with our proposal as discussed in section I.F. of this proposed rule, for the purposes of establishing the FY 2022 MS–DRG relative weights, we are proposing to use the FY 2019 MedPAR claims data, based on claims received by CMS through March 31, 2020, and the March 2020 update of the FY 2018 HCRIS file where we ordinarily would have used the FY 2020 MedPAR claims data, based on claims received by CMS through December 31, 2020, and the December 2020 update of the FY 2019 HCRIS file. We refer the reader to section I.F. of this

proposed rule for further discussion of our analysis of the best available data for purposes of the FY 2022 ratesetting and our related proposals.

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2022, we are proposing to use two data sources: Claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2019 MedPAR data used in this proposed rule include discharges occurring on October 1, 2018, through September 30, 2019, based on bills received by CMS through March 31, 2020, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2019 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,217,828 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the March 31, 2020 update of the FY 2019 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2022 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2022 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2019 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2022 GROUPER (Version 39).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. However, as discussed earlier in this section, we are proposing to use the March 31, 2020 update of the FY 2018 HCRIS for calculating the proposed FY 2022 cost-based relative weights. Consistent with our historical practice, for this FY 2022 proposed rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2022 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.'' We note that this file is identical to the file used for the FY 2021 IPPS/LTCH PPS final rule. As discussed previously, we are also making available the FY 2019 HCRIS and the FY 2020 MedPAR file as well as other related information and data files for purposes of public comment on our alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting.

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the proposed FY 2022 relative weights based on 19 CCRs, as we did for FY 2021. The methodology we are proposing to use to calculate the FY 2022 MS–DRG cost-based relative weights based on claims data in the FY 2019 MedPAR file and data from the FY 2018 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2022 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2019 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 to 58842). For FY 2022 and subsequent years, we are proposing to subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.8 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.

• Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2021, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2022, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2021 IPPS/LTCH PPS final rule, we are also proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations. The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2018 cost report data, consistent with our proposed FY 2022 ratesetting discussed in section II.A.4 of the Addendum of this proposed rule.

The 19 cost centers that we used in the proposed relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this proposed rule and available at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights

in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2022 proposed rule, this calculation was applied to address non-monotonicity for cases that grouped to MS–DRG 504 and MS–DRG 505. We note that cases were also combined in calculating the relative weights for these two MS–DRGs for FY 2021. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2022 relative weights and the changes in relative weights from FY 2021.

b. Relative Weight Calculation for MS–DRG 018

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58599 through 58600), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. We refer the reader to section II.D.2. of this proposed rule for discussion of the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies that we are proposing for assignment to MS–DRG 018 for FY 2022.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized our proposals to modify our existing relative weight methodology to ensure that the relative weight for new MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs, with additional refinements in response to comments. For cases that group to MS–DRG 018, we finalized to not include claims determined to be clinical trial claims that group to new MS–DRG 018 when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). We also finalized our proposal to calculate an adjustment to account for the CAR T-cell therapy cases determined to be clinical trial cases, as described in the FY 2021 IPPS/LTCH PPS final rule, with the additional refinement of including revenue center 891 in our calculation of standardized drug charges for MS–DRG 018. Applying this finalized methodology, based on the March 2020 update of the FY 2019 MedPAR file for the FY 2021 IPPS/LTCH PPS final rule, we estimated that the average costs of CAR T-cell therapy cases determined to be clinical trial cases ($46,062) were 17 percent of the average costs of CAR T cell therapy cases determined to be non-clinical trial cases ($276,042), and therefore, in calculating the national average cost per case for purposes of the FY 2021 IPPS/LTCH PPS final rule, each case identified as a clinical trial case was adjusted by 0.17. We also noted that we were applying this adjustor for cases determined to be CAR T-cell therapy clinical trial cases for purposes of budget neutrality and outlier simulations. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for complete discussion of our finalized modifications to the relative weight calculation for MS–DRG 018.

Since we are proposing to use the same FY 2019 MedPAR claims data for FY 2022 ratesetting that we did for the FY 2021 final rule, we are also proposing to continue to use the same process to identify clinical trial claims in the FY 2019 MedPAR for purposes of calculating the FY 2022 relative weights. We continue to use the proxy of standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell biological products in the MedPAR data used for the FY 2021 final rule and this proposed rule. Using the same methodology from the FY 2021 IPPS/LTCH PPS final rule, we are proposing to apply an adjustment to account for the CAR T cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs:

- Calculate the average cost for cases to be assigned to new MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to new MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as clinical trial cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Additionally, we are continuing our finalized methodology for calculating this payment adjustment, such that: (a) When the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2019 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000. Consistent with our proposal to use the FY 2019 data for the FY 2022 ratesetting, we are also proposing to calculate this adjustor based on the March 2020 update of the FY 2019 MedPAR file for purposes of establishing the FY 2022 relative weights. Accordingly, as we did for FY 2021, we are proposing to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 17 percent to the applicable clinical trial cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this proposed rule, each case identified as a clinical trial case was adjusted by 17 percent. As we did for FY 2021, we are proposing to apply this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations.

As discussed in section I.F. of this proposed rule, we are also soliciting

comments on an alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of the FY 2022 rulemaking, which we may consider finalizing for FY 2022 based on consideration of comments received. We note that using the methodology as finalized in the FY 2021 IPPS/LTCH PPS final rule, we calculated an adjustor of 0.25 based on this alternative approach of using the FY 2020 MedPAR file.

3. Development of Proposed National Average CCRs

Consistent with our proposal to use the FY 2019 data for the FY 2022 ratesetting, as discussed earlier in this section, we are proposing to continue to use the national average CCRs that were calculated for the FY 2021 final rule using that same data. Specifically, we calculated these national average CCRs as follows:

Using the FY 2018 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight.

The proposed FY 2022 cost-based relative weights were then normalized by an adjustment factor of 1.820783 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2022 are as follows:

Group	CCR
Routine Days	0.421
Intensive Days	0.344
Drugs	0.187
Supplies & Equipment	0.297
Implantable Devices	0.293
Inhalation Therapy	0.147
Therapy Services	0.288
Anesthesia	0.071
Labor & Delivery	0.359

Group	CCR
Operating Room	0.167
Cardiology	0.094
Cardiac Catheterization	0.1
Laboratory	0.107
Radiology	0.136
MRIs	0.07
CT Scans	0.034
Emergency Room	0.147
Blood and Blood Products	0.271
Other Services	0.343

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2022. Using data from the FY 2019 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2022, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2021 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2021 to FY 2022. The crosswalk table is as follows.

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2021relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2021 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

F. Add-On Payments for New Services and Technologies for FY 2022

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs. The regulations at 42 CFR 412.87 implement these provisions and 42 CFR 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d). We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs. In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion of the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1)

Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2022 are presented in a data file that is available, along with the other data files associated with the FY 2021 IPPS/LTCH PPS final rule and correction notice, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2023 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2022 proposed rule, by clicking on the FY 2022 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We note, for the reasons discussed in section I.F of the preamble of this proposed rule, we are proposing to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of proposed FY 2022 ratesetting. We refer the reader to section I.F. of the preamble of this proposed rule for further discussion of our analysis of the best available data for FY 2022 ratesetting and our related proposals. For the FY 2023 proposed threshold values, consistent with our proposal, we are proposing to use FY 2019 claims data to evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the proposed FY 2022 standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge (using FY 2019 claims data) for all cases in the MS–DRG (using FY 2019 claims data) to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs), rather than the FY 2020 data we would otherwise use. As discussed in section I.F of the preamble of this proposed rule, we are also considering, as an alternative to our proposal, the use of the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting. If we were to finalize this alternative approach for FY 2022, we would use the FY 2020 claims data for purposes of the final thresholds for applications for new technology add-on payments for FY 2023 in the FY 2022 IPPS/LTCH PPS final rule. We are making available the threshold values calculated using the FY 2020 claims data at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001 final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or

ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Cinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that although we are affiliated with the FDA and we do not question the FDA's regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our determination of what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and efficacy on which the FDA relies but on a demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

c. Alternative Inpatient New Technology Add-On Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by the FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by the FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for a complete discussion on this policy. We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS will review the application based on the information provided by the applicant under the alternative pathway specified by the applicant. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. This policy is codified at § 412.87(c). Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program will need to meet the cost criterion under § 412.87(b)(3), and will be considered new as reflected in § 412.87(c)(2). We note, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for a complete discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We codified this policy at § 412.87(d). Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA

as a QIDP or approved under the LPAD pathway will need to meet the cost criterion under § 412.87(b)(3), and will be considered new as reflected in § 412.87(d)(2).

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for a complete discussion on this policy. We note, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

d. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for complete discussion on the increase in the new technology add on payment beginning with discharges on or after October 1, 2019.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

e. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance when considering eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

Additionally, in the FY 2021 IPPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided

that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

f. Council on Technology and Innovation (CTI)

The Council on Technology and Innovation at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS website, in a user friendly format. This guide was published in 2010 and is available on the CMS website at: *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf*.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

g. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2023 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2023, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347.

As discussed previously, in the FY 2020 IPPS/LTCH PPS final rule, we adopted an alternative inpatient new technology add-on payment pathway for certain transformative new devices and for Qualified Infectious Disease Products, as set forth in the regulations at § 412.87(c) and (d). The change in burden associated with these changes to the new technology add-on payment application process were discussed in a revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347. In accordance with the implementing regulations of the PRA, we detailed the revisions of the ICR and published the required 60-day notice on August 15, 2019 (84 FR 41723) and 30-day notice on December 17, 2019 (84 FR 68936) to solicit public comments.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2022 prior to publication of this FY 2022 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on October 16, 2020 (85 FR 65815), and held a virtual town hall meeting on December 15 and 16, 2020. In the announcement notice for the meeting,

we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2022 new medical service and technology add on payment applications before the publication of the FY 2022 IPPS/LTCH PPS proposed rule.

Approximately 330 individuals registered to attend the 2-day virtual town hall meeting. We posted the recordings of the 2-day virtual town hall on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*. We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 28, 2020 deadline, in our evaluation of the new technology add on payment applications for FY 2022 in the development of this FY 2022 IPPS/LTCH PPS proposed rule.

In response to the published notice and the December 15–16, 2020 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2022 new technology add on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (85 FR 65815 through 65817), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2022. Therefore, we are not summarizing those written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.H.5. of the preamble of this proposed rule, we are summarizing comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/medicare/icd-10/2021-icd-10-pcs*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. Proposed FY 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments

In this section of the proposed rule, we discuss the proposed FY 2022 status of 23 technologies approved for FY 2021 new technology add-on payments, as set forth in the tables that follow. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We refer the reader to section II.F.6.b.(1). of the preamble of this proposed rule for discussion of CONTEPO, which we conditionally approved for FY 2021 new technology add-on payments under the alternative pathway for certain antimicrobial products, subject to the technology receiving FDA marketing authorization by July 1, 2021. As of the time of the development of this proposed rule, CONTEPO has not yet received FDA marketing authorization.

a. Proposed Continuation of New Technology Add-On Payments for FY 2022 for Technologies Still Considered To Be New

In the table in this section of the proposed rule, we present our proposals to continue the new technology add-on payment for FY 2022 for those technologies that were approved for the new technology add-on payment for FY 2021 and which would still considered ''new'' for purposes of new technology add-on payments for FY 2022.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

The table in this section lists the technologies for which we are proposing to continue making new technology add-on payments for FY 2022 because they would still be considered new for purposes of new technology add-on payments. This table also presents the newness start date, new technology add-on payment start date, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

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Proposed Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments Still Considered New for FY 2022							
Technology		**FDA/ Newness Start Date**	**NTAP start date**	**Proposed NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
1	*Balversa™*	*4/12/2019*	*10/1/2019*	*Propose to continue because 3-year anniversary date (4/12/2022) will occur in the second half of FY 2022*	(84 FR 42237 through 42242) and (85 FR 58616)	$3,563.23	XW0DXL5
2	*Jakafi®*	*5/24/2019*	*10/1/2019*	*Propose to continue because 3-year anniversary date (5/24/2022) will occur in the second half of FY 2022*	(84 FR 42265 through 42273) and (85 FR 58617 through 58618)	$4,096.21	XW0DXT5
3	*BAROSTIM NEO™ System*	*08/16/2019*	*10/1/2020*	*Propose to continue because 3-year anniversary date (8/16/2022) will occur in the second half of FY 2022*	(85 FR 58716 through 58717)	$22,750	0JH60MZ in combination with 03HK0MZ or 03HL0MZ
4	*FETROJA® (Cefiderocol)*	*11/19/2019 commercially available in US 2/24/2020*	*10/1/2020*	*Propose to continue because 3-year anniversary date (2/24/2023) will occur after FY 2022*	(85 FR 58721 through 58723)	$7,919.86	XW03366 or XW04366

Proposed Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments Still Considered New for FY 2022							
Technology		**FDA/ Newness Start Date**	**NTAP start date**	**Proposed NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
5	*Optimizer® System*	*10/23/2019*	*10/1/2020*	*Propose to continue because 3-year anniversary date (10/23/2022) will occur after FY 2022*	(85 FR 58720 through 58721)	$14,950	0JH60AZ, 0JH63AZ, 0JH80AZ or 0JH83AZ
6	*RECARBRIO™*	*07/16/2019 commercially available in US 1/6/2020*	*10/1/2020*	*Propose to continue because 3-year anniversary date (1/6/2023) will occur after FY 2022*	(85 FR 58727 through 58729)	$3,532.78	XW033U5 or XW043U5
7	*Soliris®*	*06/27/2019*	*10/1/2020*	*Propose to continue because 3-year anniversary date (6/27/2022) will occur in second half of FY 2022*	(85 FR 58684 through 58689)	$21,199.75	XW033C6 and XW043C6
8	*XENLETA™*	*08/19/2019 commercially available in US 9/10/2019*	*10/1/2020*	*Propose to continue because 3-year anniversary date (9/10/2022) will occur in the second half of FY 2022*	(85 FR 58729 through 58732)	$1,275.75	XW03366, XW04366 or XW0DX66
9	*ZERBAXA®*	*06/03/2019*	*10/1/2020*	*Propose to continue because 3-year*	(85 FR 58732	$1,836.98	XW03396 or XW04396

Proposed Continuation of Technologies Approved for FY 2021 New Technology Add-on Payments Still Considered New for FY 2022							
Technology		FDA/ Newness Start Date	NTAP start date	Proposed NTAP Status for FY 2022	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2022	Coding Used to Identify Cases Eligible for NTAP
				anniversary date (6/3/2022) will occur in the second half of FY 2022	through 58733)		

b. Proposal To Extend New Technology Add-On Payments

Section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. As explained in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Generally, we use FDA approval (that is, marketing authorization) as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRGs. The costs of the new medical service or technology, once paid for by Medicare for this 2-year to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, we limit the add-on payment window for those technologies that have passed this 2- to 3-year timeframe.

As discussed in the FY 2006 IPPS final rule (70 FR 47349) and subsequent years, we do not believe that case volume is a relevant consideration for making the determination as to whether a product is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we have historically considered its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent.

However, in light of the unique circumstances for FY 2022 ratesetting, for which we are proposing to use the FY 2019 MedPAR claims data where we ordinarily would have used the FY 2020 MedPAR claims data for purposes of developing the FY 2022 relative weights, for the reasons discussed in section I.F. of the preamble of this proposed rule, we believe it may be appropriate to make a one-time exception to this long-standing policy for all technologies approved for new technology add-on payments for FY 2021, but for which the add-on payments would otherwise be discontinued beginning in FY 2022 because the technologies would no longer be considered new.

As discussed in section I.F. of the preamble of this proposed rule, ordinarily, the best available MedPAR data for ratesetting would be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. For FY 2022 ratesetting, under ordinary circumstances, the best available data would be the FY 2020 MedPAR file. As discussed in section I.F. of the preamble of this proposed rule, the FY 2020 MedPAR claims file contains data significantly impacted by the COVID–19 PHE, primarily in that the utilization of inpatient services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. Accordingly, we question whether the FY 2020 MedPAR claims file is the best available data to use for the FY 2022 ratesetting.

In our discussion in section I.F. of the preamble of this proposed rule, we highlighted two factors we considered in assessing which data sources would represent the best available data to use in the FY 2022 ratesetting. The first factor is whether the FY 2019 data, which is from before the COVID–19 PHE, or the FY 2020 data, which includes the COVID–19 PHE time period, is a better overall approximation of the FY 2022 inpatient experience. After analyzing this issue, for the reasons discussed in section I.F. of the preamble of this proposed rule, we believe for purposes of this proposed rule that FY 2019 data are generally a better overall approximation of FY 2022. The second factor is to what extent the decision to use the FY 2019 or FY 2020 data differentially impacts the FY 2022 IPPS ratesetting. As discussed more fully in section I.F of the preamble of this proposed rule, after analyzing this issue, we determined that the decision does differentially impact the overall FY 2022 IPPS ratesetting. For example, we determined that the effect on the FY 2022 MS–DRG relative weights is more limited if the FY 2019-based weights are used rather than the FY 2020-based weights, should the FY 2022 inpatient experience not match the assumption used to calculate the MS–DRG relative weights.

Based on our analyses, we are proposing to use FY 2019 data for the FY 2022 ratesetting for circumstances

where the FY 2020 data is significantly impacted by the COVID–19 PHE. Because we believe the FY 2020 MedPAR claims data is significantly impacted by the COVID–19 PHE, we are proposing to use the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, including for purposes of developing the FY 2022 relative weights. We refer the reader to section I.F. of the preamble of this proposed rule for a further discussion on our analysis of the best available data for FY 2022 ratesetting.

As discussed previously, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because we are proposing to use FY 2019 MedPAR data instead of FY 2020 MedPAR data for the FY 2022 IPPS ratesetting, the costs for a new technology for which the 3-year anniversary date of the product's entry onto the U.S. market occurs prior to the latter half of the upcoming fiscal year (FY 2022) may not be fully reflected in the MedPAR data used to recalibrate the MS–DRG relative weights for FY 2022. Therefore, in light of our proposal to use FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights, we believe it would be appropriate to allow for a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022. Accordingly, we are proposing to use our authority under section 1886(d)(5)(I) of the Act to provide for a one-year extension of new technology add-on payments for FY 2022 for those technologies listed in the table that follows. We note that if we were to finalize our alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, including development of the FY 2022 relative weights, as discussed in section I.F. of the preamble of this proposed rule, we would also finalize to discontinue the new technology add-on payments for these expiring technologies beginning in FY 2022, consistent with our historic policies.

We note that this table also presents the newness start date, new technology add-on payment start date, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for these technologies. We refer readers to the final rules cited in the table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We are inviting public comment on our proposal to use our authority under section 1886(d)(5)(I) of the Act to provide for a 1-year extension of new technology add-on payments for FY 2022 for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

We finally note, with regard to ContaCT which is a technology sold on a subscription basis, we continue to welcome comments from the public as to the appropriate method to determine a cost per case for technologies sold on a subscription basis, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

Proposed One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022							
Technology		**FDA/ Newness Start Date**	**NTAP start date**	**Proposed NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
1	*Azedra®*	*7/30/2018*	*10/1/2019*	*Propose a one year extension; 3-year anniversary date (7/30/2021) will occur prior to the second half of FY 2022*	(84 FR 42194 through 42201) and (85 FR 58615)	$98,150	XW033S5 and XW043S5
2	*Cablivi®*	*2/6/2019*	*10/1/2019*	*Propose a one year extension; 3-year anniversary date (2/6/2022) will occur prior to the second half of FY 2022*	(84 FR 42201 through 42208) and (85 FR 58615)	$33,215	XW013W5, XW033W5 and XW043W5
3	*Elzonris™*	*12/21/2018*	*10/1/2019*	*Propose a one year extension;3-year anniversary date (12/21/2021) will occur prior to the second half of FY 2022*	(84 FR 42231 through 42237) and (85 FR 58615 through 58616)	$125,448.05	XW033Q5 and XW043Q5

Proposed One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022							
Technology		**FDA/ Newness Start Date**	**NTAP start date**	**Proposed NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
4	*AndexXa™*	*5/3/2018*	*10/1/2018*	*Propose a one year extension; 3-year anniversary date (5/3/2021) will occur prior to the second half of FY 2022*	(83 FR 41355 through 41362), (84 FR 42193 through 42194) and (85 FR 58614 through 58615)	$18,281.25	XW03372 or XW04372
5	*Spravato®*	*3/5/2019*	*10/1/2019*	*Propose a one year extension; 3-year anniversary date (3/5/2022) will occur prior to the second half of FY 2022*	(84 FR 42247 through 42256) and (85 FR 58616 through 58617)	$1,014.79	XW097M5
6	*Zemdri®*	*6/25/2018*	*10/1/2018*	*Propose a one year extension; 3-year anniversary date (6/25/2021) will occur prior to the second half of FY 2022*	(83 FR 41326 through 41334), (84 FR 42190 through 42191) and 85 FR 58613)	$4,083.75	XW033G4 and XW04G4
7	*T2 Bacteria® Panel*	*5/24/2018*	*10/1/2019*	*Propose a one year extension; 3-year anniversary date (5/24/2021) will occur*	(84 FR 42278 through 42288) and (85 FR 58618)	$97.50	XXE5XM5

Proposed One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022							
Technology		**FDA/ Newness Start Date**	**NTAP start date**	**Proposed NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
				prior to the second half of FY 2022			
8	*ContaCT*	*02/13/2018 (commercially available 10/01/2018)*	*10/1/2020*	*Propose a one year extension; 3-year anniversary date (10/1/2021) will occur prior to the second half of FY 2022*	(85 FR 58625 through 58636)	$1,040	4A03X5D
9	*Eluvia™ Drug-Eluting Vascular Stent System*	*09/18/2018 commercially available in US 10/4/2018*	*10/1/2020*	*Propose a one year extension; 3-year anniversary date (10/4/2021) will occur prior to the second half of FY 2022*	(85 FR 58645 through 58636)	$3,646.50	X27H385, X27H395, X27H3B5, X27H3C5, X27J385, X27J395, X27J3B5, X27J3C5, X27K385, X27K395, X27K3B5, X27K3C5, X27L385, X27L395, X27L3B5, X27L3C5
10	*Hemospray®*	*05/07/2018 (commercially available 07/01/2018)*	*10/1/2020*	*Propose a one year extension; 3-year anniversary date (07/01/2021) will occur prior to the second half of FY 2022*	(85 FR 58665 through 58672)	$1,625	XW0G886 and XW0H886
11	*IMFINZI®/ TECENTRIQ®*	*Imfinzi: 03/27/2020;*	*10/1/2020*	*Propose a one year extension; 3-*	(85 FR 58672	$6,875.90	Imfinzi XW03336 or XW04336

Proposed One Year Extension for Technologies for which New Technology Add-on Payment Would Otherwise Be Discontinued in FY 2022							
Technology		**FDA/ Newness Start Date**	**NTAP start date**	**Proposed NTAP Status for FY 2022**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2022**	**Coding Used to Identify Cases Eligible for NTAP**
		Tecentriq: 03/18/2019 *Newness date is 3/18/2019 for both*		*year anniversary date (3/18/2022) will occur prior to the second half of FY 2022*	through 58684)		Tecentriq XW033D6 or XW043D6
12	*NUZYRA®*	*10/02/2018 (commercially available 02/01/2019)*	*10/1/2020*	*Propose a one year extension; 3-year anniversary date (2/1/2022) will occur prior to the second half of FY 2022*	(85 FR 58725 through 58727)	$1,552.50	XW033B6 or XW043B6
13	*SpineJack® System*	*08/30/2018 (commercially available 10/11/2018)*	*10/1/2020*	*Propose a one year extension; 3-year anniversary date (10/11/2021) will occur prior to the second half of FY 2022*	(85 FR 58689 through 58701)	$3,654.72	XNU0356 and XNU4356
14	*Xospata®*	*11/28/2018*	*10/1/2019*	*Propose a one year extension; 3-year anniversary date (11/28/2021) will occur prior to the second half of FY 2022*	(84 FR 42256 through 42260) and (85 FR 58617)	$7,312.50	XW0DXV5

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5. FY 2022 Applications for New Technology Add-On Payments (Traditional Pathway)

a. Aidoc Briefcase for PE

Aidoc Medical Ltd. (Aidoc) submitted an application for new technology add-on payments for Aidoc Briefcase for PE (''Briefcase for PE'') for FY 2022. According to the applicant, Briefcase for PE is an FDA cleared, artificial intelligence (AI)-based solution for triage and notification of suspected pulmonary embolism (PE) cases.

The applicant stated that the device assists hospitals and radiologists by flagging and communicating suspected positive findings of PE in computed tomography (CT) pulmonary angiography (CTPA) examinations, which prompts the radiologist to assess relevant Digital Imaging and Communications in Medicine (DICOM) imaging files, allowing suspect cases to receive attention sooner than otherwise would have occurred, which in turn improves clinical outcomes. According to the applicant, patients with PE or suspected PE typically present at hospital emergency departments (EDs). The applicant stated that for these patients, ED physicians complete a brief evaluation and order imaging, which typically includes CTPA. With Briefcase for PE, CTPA images are automatically forwarded to the applicant's cloud-based engine where they are analyzed by an AI algorithm. The applicant claims that when Briefcase for PE detects a suspected PE, the radiologist is alerted via the user interface of the Aidoc Worklist Application that is installed on the radiologist's desktop. The applicant asserted that the notification prompts the radiologist to review the CTPA images and communicate with the emergency room team currently caring for the patient so that the appropriate clinical action may be taken sooner than it would otherwise have occurred in the absence of the tool.

The applicant stated that acute PE is a severe manifestation of venous thromboembolism (VTE) and occurs when a blood clot (thrombus) forms in a vein and then dislodges and travels to the pulmonary arteries in the lungs. The applicant stated acute symptomatic PE can cause death within 1 hour of onset in up to 10 percent of cases [7] and it is estimated to be the third largest cause of cardiovascular death after coronary artery disease and stroke.[8] [9] [10] [11] The applicant further noted that acute PE is a life-threatening medical emergency that demands urgent intervention and clinical studies have demonstrated a strong correlation between time to communication of PE findings, treatment, and clinical outcomes.[12] [13] [14] According to the applicant, in a typical workflow, a patient presenting to a hospital with signs or symptoms of PE would move through the system as follows: (1) Patient presents with suspected PE to the ED; (2) Patient receives contrast-enhanced CTPA imaging; (3) Technologist processes and reconstructs the CT images and manually routes them to the hospital picture archiving and communication system (PACS); (4) The exam enters a first-in-first-out (FIFO) reading queue, where it awaits radiological interpretation; (5) Radiologist reads the CT images and makes the diagnosis of PE; (6) The radiologist informs the referring physician of positive PE either verbally or through the radiologist report; (7) ED physician and/or on-call pulmonologist decide on the management strategy; (8) If appropriate, the patient proceeds to treatment.

The applicant asserted that the FIFO workflow is the standard of care. The applicant stated that Briefcase for PE allows facilities to substantially shorten the period of time between when the patient receives CTPA imaging (Step 2) and when the radiologist informs the referring physician of positive PE (Step 5). The applicant stated that Briefcase for PE streamlines this workflow using AI to analyze CTPA images of the chest automatically and notifies the radiologist that a suspected PE has been identified, enabling the radiologist to review imaging and make diagnostic decisions faster by prioritizing these images for review in the queue.

With respect to the newness criterion, Briefcase for PE received FDA 510(k) clearance on April 15, 2019 to market the device under FDA 510(k) number K190072. The FDA clearance for Briefcase for PE was based on substantial equivalence to the legally marketed predicate device, Briefcase for Intracranial Hemorrhage (ICH) (FDA 510(k) number K180647), as both of these devices use AI algorithms to analyze images and highlight cases for further action based on CT images. Briefcase for ICH received FDA 510(k) clearance on August 1, 2018. The predicate device for Briefcase for ICH is Viz.AI's ContaCT, which received De Novo premarket approval in February of 2018. The applicant asserted Briefcase for ICH is indicated for use in the analysis of non-enhanced head CT images, whereas Briefcase for PE is indicated for use in the analysis of non-enhanced CTPA images. According to the applicant, there are currently no ICD–10–PCS procedure codes to adequately describe Briefcase for PE. The applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology beginning FY 2022.

Under the newness criterion, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Briefcase for PE is the only FDA-cleared technology that uses computer-aided triage and notification to rapidly detect PE and shorten time to notification of the radiologist. The applicant claimed that no other FDA approved or cleared technology uses the same mechanism of action for computer-aided triage and prioritization of PE.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated it expects that patients evaluated for PE or suspected PE using Briefcase for PE will be assigned to the

[7] Naess IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrøm J. Incidence and mortality of venous thrombosis: A population-based study. *J Thromb Haemost.* 2007 Apr;5(4):692–9. doi: 10.1111/j.1538–7836.2007.02450.x. PMID: 17367492.

[8] Giuntini C, Di Ricco G, Marini C, Melillo E, Palla A. Pulmonary embolism: Epidemiology. *Chest.* 1995 Jan;107(1 Suppl):3S–9S. doi: 10.1378/chest.107.1_supplement.3s. PMID: 7813326.

[9] Becattini C, Agnelli G. Risk factors for adverse short-term outcome in patients with pulmonary embolism. *Thromb Res.* 2001 Sep 15;103(6):V239–44. doi: 10.1016/s0049–3848(01)00291–2. PMID: 11567661.

[10] Goldhaber SZ, Visani L, De Rosa M. Acute pulmonary embolism: Clinical outcomes in the International Cooperative Pulmonary Embolism Registry (ICOPER). *Lancet.* 1999 Apr 24;353(9162):1386–9. doi: 10.1016/s0140–6736(98)07534–5. PMID: 10227218.

[11] Klok FA, Mos IC, Huisman MV. Brain-type natriuretic peptide levels in the prediction of adverse outcome in patients with pulmonary embolism: A systematic review and meta-analysis. *Am J Respir Crit Care Med.* 2008 Aug 15;178(4):425–30. doi: 10.1164/rccm.200803–459OC. Epub 2008 Jun 12. PMID: 18556626.

[12] Smith SB, Geske JB, Maguire JM, Zane NA, Carter RE, Morgenthaler TI. Early anticoagulation is associated with reduced mortality for acute pulmonary embolism. *Chest.* 2010 Jun;137(6):1382–90. doi: 10.1378/chest.09–0959. Epub 2010 Jan 15. PMID: 20081101; PMCID: PMC3021363.

[13] Soh S, Kim JM, Park JH, Koh SO, Na S. Delayed anticoagulation is associated with poor outcomes in high-risk acute pulmonary embolism. J Crit Care. 2016 Apr;32:21–5. doi: 10.1016/j.jcrc.2015.11.024. Epub 2015 Dec 8. PMID: 26764578.

[14] Wood KE. Major pulmonary embolism: Review of a pathophysiologic approach to the golden hour of hemodynamically significant pulmonary embolism. *Chest.* 2002 Mar;121(3):877–905. PMID: 11888976.

same DRGs as patients evaluated for PE or suspected PE under the current workflow or standard of care. The applicant estimates that under the MS–DRG grouper for FY 2021, Briefcase for PE could map to 279 different MS–DRGs, with MS–DRGs 175 (Pulmonary embolism with major complication or comorbidity (MCC) or acute cor pulmonale) and 176 (Pulmonary embolism without MCC) accounting for approximately 45 percent of the estimated cases.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant did not directly respond to the criterion but reiterated that no other existing technology is comparable to Briefcase for PE and that Briefcase for PE is the only FDA-cleared technology that uses computer aided triage and notification to rapidly detect PE and shorten time to notification of the radiologist.

We have the following concerns regarding whether the technology meets the substantial similarity criteria and whether it should be considered new. We note that the applicant asserted that Briefcase for ICH, the predicate device for Briefcase for PE, is identical in all aspects and differs only with respect to the training of the algorithm on PE (that is, non-enhanced head CT) and ICH (that is, non-enhanced CTPA) images. We are unclear whether the training of the algorithim on PE and ICH images would distinguish the mechanism of action for Briefcase for PE from Briefcase for ICH, or its predicate device, ContaCT, and we invite comment on whether Briefcase for PE represents a new mechanism of action. We note that although the applicant did not directly state whether Briefcase for PE involves the treatment of the same or similar type of disease and the same or similar patient population, we believe that Briefcase for PE would be used for a different disease and patient population than Briefcase for ICH and ContaCT.

We continue to be interested in public comments regarding issues related to determining newness for technologies that use AI, an algorithm, or software, as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58628). Specifically, we are interested in public comment on how these technologies, including devices classified as radiological computer aided triage and notification software and radiological computer-assisted diagnostic software, may be considered for the purpose of identifying a unique mechanism of action; how updates to AI, an algorithm or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology.

We invite public comments on whether Briefcase for PE meets the newness criterion.

With regard to the cost criterion, the applicant presented the following analysis. The applicant first identified the principal diagnoses associated with the PE-related MS–DRGs 175 (''Pulmonary embolism with MCC or acute cor pulmonale'') and 176 (''Pulmonary embolism without MCC''). The applicant then searched the FY 2019 proposed rule MedPAR Limited Data Set (LDS) for claims where the principal diagnoses were listed in any position on an inpatient claim. The applicant mapped the 2,517 identified claims to the list of unique MS–DRGs corresponding to these claims and aggregated the claims by MS–DRG. Per the applicant, under the MS–DRG grouper for FY 2021, potential cases representing patients who may be eligible for treatment using Briefcase for PE map to 279 MS–DRGs, with MS–DRGs 175 and 176 accounting for approximately 45 percent of estimated cases. The applicant also provided a table of the top 10 MS–DRGs, which represent approximately 69 percent of estimated cases.

MS-DRG	MS-DRG Title
175	PULMONARY EMBOLISM WITH MCC OR ACUTE COR PULMONALE
176	PULMONARY EMBOLISM WITHOUT MCC
871	SEPTICEMIA OR SEVERE SEPSIS WITHOUT MV >96 HOURS WITH MCC
299	PERIPHERAL VASCULAR DISORDERS WITH MCC
208	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT <=96 HOURS
291	HEART FAILURE AND SHOCK WITH MCC
280	ACUTE MYOCARDIAL INFARCTION, DISCHARGED ALIVE WITH MCC
163	MAJOR CHEST PROCEDURES WITH MCC
270	OTHER MAJOR CARDIOVASCULAR PROCEDURES WITH MCC
853	INFECTIOUS AND PARASITIC DISEASES WITH O.R. PROCEDURES WITH MCC

The applicant standardized the charges and applied the 2-year charge inflation factor used to adjust the outlier threshold determination, which the applicant stated was 10.22 percent. We note that the actual 2-year inflation factor in the FY 2021 IPPS/LTCH PPS final rule was 13.2 percent (85 FR 59039), which would have increased the inflated charges figure. The applicant did not remove charges for prior technology as the applicant maintained that no existing technology is comparable to Briefcase for PE. However, the applicant removed 31.9 percent of total accommodation charges, which the applicant maintained is consistent with their internal study which indicated that Briefcase for PE reduced the length of stay for PE-diagnosed patients.[15] Per the applicant, the study demonstrated a mean length of stay of 8.77 and 5.97 days for pre-AI and post-AI time periods, respectively.[16]

Next, the applicant added charges for the new technology. To calculate the charges for the new technology, the applicant multiplied the cases involving Briefcase for PE from each of its subscribing providers by a Medicare share of 52 percent to obtain the total estimated Medicare and non-Medicare cases. The applicant obtained the 52 percent Medicare share figure from a

[15] Maya M. et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduced Length of Stay. Abstract draft of an internal study performed by the applicant (unpublished).

[16] Ibid.

nationwide sample of inpatient claims provided by the Agency for Healthcare Research and Quality (AHRQ). Specifically, the applicant searched data from the Healthcare Cost and Utilization Project for discharges with the following codes: I2699, I2609, I2692, I2602, I2782, T790XXA, T800XXA, T791XXA, I2693, I2694, and I2601.[17] The applicant found 189,575 discharges, of which 52 percent identified Medicare as the payer. The applicant divided the total cost of the technology by the estimated total number of cases for each customer to obtain a provider-specific cost per case, which it then averaged across all customers to obtain an overall average cost per case. Finally, the applicant divided the average cost per case by the national average CCR for the CT cost center of 0.034 from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601).

The applicant calculated a final inflated average case-weighted standardized charge per case of $87,483, which exceeded the average case-weighted threshold amount of $71,312. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that Briefcase for PE meets the cost criterion.

We would like more information regarding the methodology by which the applicant selected the diagnosis codes associated with MS–DRGs 175 and 176, as well as subanalyses that limit the cases to MS–DRGs 175 and 176 and the top 10 MS–DRGs, which per the applicant represent 45 percent of estimated cases and 69 percent of estimated cases, respectively. Additionally, the applicant appears to have used a single list price of Briefcase for PE per hospital with a cost per patient that can vary based on the volume of cases. We question whether the cost per patient varies based on the utilization of the technology by the hospitals. We are interested in more information about the applicant's cost per case calculation, including how the applicant selected the codes it used to search for discharges from the Healthcare Cost and Utilization Project, as well as the per unit cost of Briefcase for PE and how the total cost of the technology was calculated for each subscribing provider.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630), we stated our understanding that there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We stated our intent to continue to consider the issues relating to the calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. We continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment. We also invite public comment on whether Briefcase for PE meets the cost criterion, particularly in light of the subscription model, for which the number of subscribers and the estimated cost per case based on that subscriber data may change over time.

With regard to the substantial clinical improvement criterion, the applicant claimed that Briefcase for PE represents an advance that substantially improves the ability to diagnose pulmonary embolism by pre-reading images of CTPAs, automatically identifying suspected PE in CTPA images, and notifying the radiologist before the radiologist would have opened the study in the standard of care, which the applicant claims is the FIFO workflow. The applicant also asserted that because of a reduction in time-to-exam-open, where Briefcase for PE notifies the radiologist to open and read CTPA studies that have a high probability of being positive for PE sooner than the radiologist would have under the FIFO workflow, the treating physician can initiate treatment sooner, which can reduce mortality and reduce length of stay related to PE.

The applicant provided data from an FDA pivotal study in support of its assertion that Briefcase for PE reduces time-to-exam-open compared to the standard of care and helps in prioritization of diagnosis.[18] For the FDA pivotal study, the applicant conducted a retrospective, blinded, multicenter, multinational study of the assessment of 184 CTPAs from 3 clinical sites (2 US and 1 outside US) using Briefcase for PE. The primary endpoint was to evaluate the software's performance in identifying pulmonary embolism on an approximately equal number of positive and negative cases (images with PE versus without PE), with a performance goal of at least 80 percent sensitivity (true positive rate) and specificity (true negative rate). Per the applicant, both measures exceeded the performance goal, with 90.6 percent sensitivity (95 percent CI: 82.2 percent–95.9 percent) and 89.9 percent specificity (95 percent CI: 82.2 percent–95.1 percent).

According to the applicant, the secondary endpoint of the FDA pivotal study was to evaluate time-to-notification for true positive PE cases compared to the FIFO workflow. The study showed that time-to-notification with Briefcase for PE is 3.9 minutes (95 percent CI: 3.7–4.1). The applicant noted that, in contrast, the time-to-exam-open in the FIFO workflow was significantly longer at 64.1 minutes (95 percent CI 36.6–91.5). The applicant stated the mean difference of 60.2 minutes (95 percent CI 32.7–87.6) for these two metrics is statistically significant, and assuming the radiologist receives a notification on a true positive PE case and acts on it immediately, it can save an average of 60.2 minutes (95 percent CI 32.7–87.6) compared to the time-to exam-open in a FIFO reading queue. Based on this data, the applicant concluded Briefcase for PE substantially shortened the time to diagnosis for PE cases as compared with the FIFO workflow.

The applicant further claimed that clinical studies and other real-world data have demonstrated comparable performance characteristics and shown that the integration of the Briefcase for PE software into the radiology workflow markedly improves time to notification for PE patients across a variety of clinical settings, geographies, and facilities. The applicant submitted a retrospective, single-site study by Weikert T., et al., which evaluated Briefcase for PE performance on 1,465 retrospective CTPA examinations from 2017 in an academic center outside the US.[19] The sensitivity and specificity were measured to be 92.7 percent (95 percent CI: 88.3–95.5 percent) and 95.5 percent (95 percent CI: 94.2–96.6 percent), respectively. The researchers concluded that the system has high diagnostic performance for the automatic detection of PE on CTPA exams and as such, speeds up the diagnostic workup of critical cases.

The applicant stated that unpublished data maintained by Aidoc suggest that real-world performance of Briefcase for PE is consistent with what was found in

[17] Healthcare Cost and Utilization Project. Free Health Care Statistics. *https://hcupnet.ahrq.gov/#setup*.

[18] Aidoc Briefcase for PE—Pivotal Study 1—FDA 510(k)—K190072. *http://www.accessdata.fda.gov/cdrh_docs/pdf19/K190072.pdf*.

[19] Weikert T, Winkel DJ, Bremerich J, Stieltjes B, Parmar V, Sauter AW, Sommer G. Automated detection of pulmonary embolism in CT pulmonary angiograms using an AI-powered algorithm. *Eur Radiol*. 2020 Jul 3. doi: 10.1007/s00330–020–06998–0. Epub ahead of print. PMID: 32621243

the FDA pivotal study.[20] [21] The applicant stated that across 26 sites encompassing a variety of geographic locations across the United States, a total of 36,084 CTPA examinations were analyzed over a 90-day period (July 13, 2020–October 11, 2020). Time-to-notification metrics were calculated for all 4,748 CTPAs analyzed by the software and identified as positive for PE. Time-to-notification was calculated as the time to get the DICOM exam, de-identify it, upload it to the cloud, analyze and send a notification back to the worklist application. The applicant claimed that the mean time-to-notification for PE was 7.0 minutes (median: 6.1/IQR: 4.8). According to the applicant, over 85 percent of CTPA examinations identified as positive for PE were notified in under 10 minutes. The applicant concluded that the study demonstrates the ability of Briefcase for PE to provide fast time-to-notification on positive PE cases and its generalizability across different centers and patient populations.

The applicant submitted additional unpublished data from the 26 sites spread across a variety of geographic locations of the United States aggregated over a different 90-day period (September 17, 2020 to December 17, 2020).[22] Seven sites were excluded from the analysis due to having third-party integrations that prevented the ability to capture engagement metrics. Two engagement metrics were calculated: The open percentage and the time-to-open. The open percentage metric was calculated as the percentage of notifications that were presented to the radiologist and opened by at least one radiologist. The time-to-open metric was measured by calculating the time between the arrival of the Briefcase for PE notification and the time first opened by a radiologist. A total of 2,138 notifications for CTPA examinations found to be positive for PE by Briefcase for PE were analyzed. The open percentage was found to be 97 percent across all sites (min: 80 percent, max: 100 percent), and the mean time-to-open was found to be 2.13 minutes (median: 1.0/interquartile range: 2.0). The data provided by the applicant indicated over 90 percent of notifications were found to be opened in under 5 minutes. Based on this data, the study concluded that radiologists in the US readily engage with notifications for positive PE cases provided by Briefcase for PE and do so in a timely manner. The study asserted that engagement is an important metric to assess radiologist adoption of this technology, which is critical to its practical utility in shortening time to diagnosis and communication of PE to reduce the time to treatment and improve clinical outcomes.

The applicant also claimed that Briefcase for PE significantly improves clinical outcomes relative to the current standard of care using the FIFO workflow because the use of Briefcase for PE reduces time to diagnosis and treatment by notifying the radiologist to review the image for suspected PE faster in the workflow. The applicant claimed early diagnosis and treatment is important in acute PE where there exists a ''golden hour,'' during which a timely approach to diagnosis and therapy can affect outcomes by reducing mortality and reducing length of stay.[23]

The applicant provided two unpublished internal studies in support of the impact of Briefcase for PE on clinical outcomes. The applicant stated that in a single-site retrospective study, Maya M., et al. have shown a reduction in hospital length of stay for PE patients following the use of the Briefcase for PE system, compared to an equivalent time period prior to the use of the system.[24] The applicant stated that Maya M., et al. compared mean length of stay for 366 patients with a positive PE diagnosis during 10-month periods before and after Briefcase for PE was implemented at Cedars-Sinai Medical Center in December 2018 (206 patients before the use of Briefcase for PE and 160 patients after the AI intervention). 3,997 patient encounters that underwent CTPA imaging but that were not diagnosed with PE were split as 1,926 and 2,071 patient encounters for the pre/post-AI periods based on the admission dates. Hip fracture was chosen as a comparison group due to acuity, treatment-related factors, and similar length of stay to PE. 2,422 patient encounters for patients diagnosed with hip fractures, identified by ICD9 code 820 and 821, were split as 1,279 and 1,143 patient encounters for the pre/post-AI periods based on the admission dates. According to the applicant, the pre- and post-implementation had similar seasonality and numbers of ''hospital-wide patient encounters'' (103,626 vs 104,733 encounters). The applicant noted that for the PE diagnosed patients, a mean length of stay of 8.77 and 5.97 days was observed for the pre-AI and post-AI time periods, respectively. The applicant stated that the mean difference was 2.80 days (p-value <0.05). For the group that underwent related PE imaging but was not diagnosed with PE, a mean length of stay of 9.28 and 9.70 days was observed for the pre-AI and post-AI time periods, respectively (mean difference was −0.42 days (p-value <0.05)). For the hip fracture diagnosed patients, a mean length of stay of 6.90 and 6.69 days was observed for the pre-AI and post-AI time periods, respectively. The mean difference was 0.21 days (p-value >0.05). Additionally, for the hospital wide patients, a mean length of stay of 5.78 and 5.96 days was observed for the pre-AI and post-AI time periods, respectively. The mean difference was −0.18 days (p-value <0.05). According to the applicant, Maya et al. concluded that implementation of Briefcase for PE for flagging and prioritization of patients with PE resulted in significant reduction of length of stay that was not observed in other control groups.

The applicant also submitted a study by Raskin D., et al. which completed an additional retrospective, single-armed, single-site, study that indicated improved outcomes in PE patients, compared to a time period prior to the use of Briefcase for PE.[25] In Raskin D., et al., data for all patients older than 18 years with a diagnosis of PE on CTPA and admitted to the institution's ED was collected for the period before the use of the AI software (January 1, 2016–January 1, 2018; pre-AI) and afterwards (January 1, 2019–December 6, 2019; post-AI). According to the applicant, study variables included demographics, clinical data, and imaging data. The applicant stated the primary variables for outcomes were 30- and 120-day all-cause mortality. 175 patients were eligible for the entire analyzed period (123 pre-AI, 52 Post-AI). The study found that 30- and 120-day all-cause mortality were significantly reduced post-AI (8.1 percent vs 7.7 percent, 15.5 percent vs 9.6 percent, respectively, p<0.05). According to the applicant, Raskin D., et al. concluded that

[20] Avondo, J. Yalon R., Ashkenasi C. Time-to-notification Analysis Across US Facilities with Aidoc Briefcase for PE. Internal study performed by the applicant (unpublished).

[21] Ibid.

[22] Avondo, J. Yalon R., Ashkenasi C. Radiologist Engagement Analysis Across US Facilities with Aidoc Briefcase for PE. Internal study performed by the applicant (unpublished).

[23] The term ''golden hour'' references a critical period of time which may be longer or shorter than a literal hour.

[24] Maya M. et al. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduced Length of Stay. Abstract draft of an internal study performed by the applicant (unpublished).

[25] Daniel Raskin D.,MD, Chen Hoffmann C.,MD, Gilad Twig G.,MD Ph.D., Eli Konen E.,MD, Gal Yaniv GMD Ph.D. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduction of Mortality. Abstract draft of an internal study performed by the applicant (unpublished).

implementation of Briefcase for PE for flagging patients with PE resulted in significant reduction of 30- and 120-day all-cause mortality.

The applicant submitted five additional clinical studies that do not directly involve the use of Briefcase for PE to demonstrate a strong correlation between time to communication of PE findings, initiation of treatment, and clinical outcomes. The applicants submitted a review by Kenneth E. Wood, further establishing a ''golden hour'' of PE during which a timely approach to diagnosis and therapy can potentially impact outcomes. According to the applicant, Wood states that major PE results whenever the combination of embolism size and underlying cardiopulmonary status interact to produce hemodynamic instability and that most deaths in patients occur within the first few hours after presentation, and rapid diagnosis and treatment is therefore essential to save patients' lives. One prospective, single-site study, Kumamaru K., et al. indicates the prevalence of a ''golden hour'' for PE diagnosis and treatment and concluded that delay (>1.5 hours of CTPA acquisition) in direct communication of acute PE diagnosis from radiologists to referring physicians was significantly correlated with a higher risk of delayed treatment initiation and death within 30 days. Another prospective, single-site study, Kline J., et al., concluded that patients with a delayed diagnosis had a higher rate of in-hospital adverse events (9 percent vs. 30 percent; p = 0.01). An additional retrospective, single-site study by Smith S., et al. observed an association between early administration of anticoagulation therapy and reduced mortality for patients with acute PE. Lastly, a retrospective, single-site study asserting a ''golden hour'' by Soh S., et al. was submitted by the applicant to demonstrate an association between early initiation of anticoagulation therapy and in-hospital mortality in high-risk PE patients who needed ICU care. According to the applicant, Soh S., et al. concluded that their analysis showed that the cutoff point of anticoagulation initiation to achieve improved survival rates was 5.2 hours (that is, golden hour). The applicant stated that the study observed an association between early anticoagulation and reduced mortality for patients with acute PE.

In reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for Briefcase for PE, we note that the clinical literature provided by the applicant only compares the technology to unassisted FIFO workflows and not against existing electronic (for example, EHR ''stat'' orders) or manual (for example, verbal communication to radiologist) forms of prioritization, or other types of existing risk stratification tools or features currently available in EHRs. Additionally, we note that some of the studies provided by the applicant that took place over many years may not have accounted for confounding variables (for example, improvements in care for patients with suspected PE) that may have occurred during the study period. Comparing to the FIFO workflow alone assumes that no other changes occurred before and after the adoption of the system and that the hospitals in question did not implement any other changes to their standard operating procedures to stratify suspected PE cases over the period of time many of the provided studies took place. We also note that the applicant has not provided data on potential outcome concerns associated with this type of clinical decision support tool (for example, treatment delays due to false negatives, false positives, or multiple workflow prioritization alerts presented to the physician at the same time). We invite public comment on whether these issues may affect the tool's ability to help diagnose a medical condition earlier in a patient population.

Lastly, we note that the applicant does not measure the effect of its technology on actual treatment outcomes, instead relying on the assumption that faster treatment results in better outcomes. Without measuring this impact on treatment outcomes, we are uncertain if the technology will lead to substantive clinical outcomes. Given that the applicant references a critical ''golden hour'' which may be as long as 5.2 hours, the potential time savings resulting from the use of Briefcase for PE may be insubstantial in relation to the time within which outcomes are affected in the setting of PE.

We are inviting public comments on whether Briefcase for PE meets the substantial clinical improvement criterion.

We received a written public comment from the applicant in response to the New Technology Town Hall meeting regarding the application of Briefcase for PE for new technology add-on payments.

Comment: The applicant responded to questions received at the New Technology Town Hall Meeting. First the applicant was asked what the sensitivity and specificity of the standalone device is for identifying pulmonary embolism and how the sensitivity and specificity of the radiologist alone compare to the sensitivity and specificity of the radiologist when using the device. The applicant responded by reiterating the sensitivity and specificity data provided in the FDA pivotal study and restating that Briefcase for PE is a computer-aided triage and notification system that is not intended to aid in the diagnosis of PE but rather, Briefcase for PE identifies cases of suspected PE on CTPAs and, via triage and notification, prioritizes these cases for radiologist review.[26] [27] The applicant further restated that this triage and notification modifies the traditional radiology workflow in which images are reviewed on a FIFO basis to reduce the time-to-open-exam from over one hour to several minutes (standard of care vs. Briefcase for PE). The applicant restated that this reduction in time-to-open-exam has been demonstrated to improve patient outcomes, including hospital length of stay and post-discharge mortality. The applicant further noted that, because Briefcase for PE is a triage and notification system, no patient harm results from false positives or false negatives that may occur. The applicant explained that with respect to false positives, these suspected cases of PE will be triaged and the radiologist will be notified, prompting earlier review and diagnosis of the CTPA image by the radiologist. The applicant explained that for cases of PE that are missed by Briefcase for PE (that is, false negatives), the radiologist will review these CTPA images on a FIFO basis the same as today's standard of care and that triage and notification do not occur in the standard of care.

Second, the applicant was asked if Briefcase for PE decreased time outside of clinical trial protocols and how the applicant can be certain reducing time-to-notification affects the time period between when the CTPA is completed and the study is interpreted. In response, the applicant again reiterated data from the FDA pivotal study in restating that implementation of Briefcase for PE saves on average 60.2 minutes relative to the standard of care FIFO clinical workflow and that data maintained by Aidoc demonstrate that real-world performance of Briefcase for PE is consistent with the results achieved in the FDA study. The

[26] Aidoc Briefcase for PE—Pivotal Study 1—FDA 510(k)—K190072. *http://www.accessdata.fda.gov/cdrh_docs/pdf19/K190072.pdf.*

[27] Weikert T, Winkel DJ, Bremerich J, et al. Automated detection of pulmonary embolism in CT pulmonary angiograms using an AI-powered algorithm. *Eur Radiol.* 2020;30(12):6545–6553. doi:10.1007/s00330–020–06998–0.

applicant also submitted data summarized previously indicating mean time-to-open, as measured by calculating the time between when a notification first became available in the application and the time of open, was 2.13 minutes (median: 1.0/IQR: 2.0). The applicant restated that in addition to measuring the mean time-to-open, the open rate, or the percentage of notifications opened, was measured for this same population and the open rate was found to be 97 percent (min: 80 percent, max: 100 percent), with over 90 percent of notifications found to be opened in under 5 minutes.[28]

Also in response to this second question, the applicant reiterated data describing an independent analysis performed by Raskin, et al., examining the impact of Briefcase for PE implementation on 30- and 120-day all-cause mortality for all patients age 18 years or older with a diagnosis of PE on CTPA and admitted to Sheba Medical Center in Tel Aviv, Israel. The applicant restated data described previously indicating that investigators found that the post- Briefcase cohort had significantly reduced 30- and 120-day all-cause mortality compared to the pre-Briefcase cohort—14.9 percent vs 11.0 percent and 26.1 percent vs 20.4 percent, respectively. The applicant stated these observed effects equate to a reduction ratio of 26.6 percent ($p < 0.05$) and an odds-ratio of 1.425 (95 CI: 1.01–2.02) for 30-day all-cause mortality and a reduction ratio of 21.8 percent ($p < 0.05$) and an odds-ratio of 1.34 (95 percent CI: 1.05–1.81) for 120-day all-cause mortality.[29]

Response: We appreciate the applicant's comments. We will take these comments into consideration when deciding whether to approve new technology add-on payments for Briefcase for PE.

[28] Avondo, J. Yalon R., Ashkenasi C. Radiologist Engagement Analysis Across US Facilities with Aidoc Briefcase for PE. Internal study performed by the applicant (unpublished).

[29] Daniel Raskin D.,MD, Chen Hoffmann C.,MD, Gilad Twig G.,MD Ph.D., Eli Konen E.,MD, Gal Yaniv GMD Ph.D. Artificial Intelligence Software for Flagging Pulmonary Embolism on CTPA Associated with Reduction of Mortality. Abstract draft of an internal study performed by the applicant (unpublished).

b. Amivantamab

Johnson & Johnson Health Care Systems, Inc. submitted an application for new technology add-on payments for amivantamab for FY 2022. Amivantamab is intended for the treatment of metastatic non-small cell lung cancer (NSCLC). The applicant stated amivantamab is a bispecific monoclonal antibody able to inhibit the epidermal growth factor receptor (EGFR) and c-MET tyrosine kinase signaling pathways known to be involved in the pathogenesis of NSCLC. Per the applicant, amivantamab works by binding EGFR and c-MET targets present on the outside of the cell. The applicant noted lung cancer is the second most common cancer in the U.S., and approximately 85 percent of all lung cancers are NSCLC. The applicant stated EGFR mutations are present in 10 to 15 percent of patients with NSCLC and are categorized as either common EGFR mutations or atypical EGFR mutations. Per the applicant, common EGFR mutations in patients with NSCLC can be treated with small molecule, oral tyrosine kinase inhibitors that work inside the cell while patients with atypical EGFR mutations, such as exon 20 insertion mutations, do not respond well to small-molecule, oral EGFR inhibitors or to chemotherapy. The applicant stated exon 20 insertion mutations are the most frequently observed atypical EGFR mutations affecting 4 to 10 percent of NSCLC patients with an EGFR mutation, but there are no FDA approved targeted therapies for NSCLC patients with exon 20 insertion mutations.

With respect to the newness criterion, the applicant stated that, in March 2020, amivantamab (also known as JNJ–61186372) received Breakthrough Therapy designation from the FDA for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutation whose disease has progressed on or after platinum-based chemotherapy. The applicant stated they are seeking a Biologics License Application (BLA) for amivantamab for the treatment of patients with metastatic NSCLC with EGFR exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy and have not yet received FDA marketing authorization. Per the applicant, amivantamab is administered as an infusion on a 28 day cycle; weekly for the first cycle and then every 2 weeks, and continued until disease progression or unacceptable toxicity. The applicant stated there are currently no ICD–10–PCS procedure codes that uniquely identify the use of amivantamab. We note the applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology beginning in FY 2022.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the mechanism of action of amivantamab for treating NSCLC is unique as amivantamab is anticipated to be the first FDA-approved bispecific antibody therapy targeting EGFR and MET mutations simultaneously. The applicant asserted that both EGFR and MET are involved in NSCLC pathogenesis, progression, and development of resistance to other therapies. According to the applicant, the most common first-line treatment for atypical EGFR-positive patients due to exon 20 insertion mutations is platinum-based chemotherapy. Per the applicant, there is no standard of care after progression for second-line treatment, and patients receive a variety of therapies such as chemotherapy, immunotherapy, and tyrosine kinase inhibitors, as well as combinations of these therapies. The applicant reiterated that none of these treatments are FDA approved for this patient population and that they are associated with limited efficacy for these patients.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the use of amivantamab is not expected to affect the DRG assignment. In their cost analysis, as shown below, the applicant identified several MS–DRGs relevant to this technology.

MS-DRG	MS-DRG Description	Cases	Percentage of Cases
871	Septicemia Or Severe Sepsis w/o Mv >96 Hours w MCC	46	13.18%
180	Respiratory Neoplasms w MCC	26	7.45%
164	Major Chest Procedures w CC	17	4.87%
193	Simple Pneumonia & Pleurisy w MCC	14	4.01%
181	Respiratory Neoplasms w CC	12	3.44%
	All Other	234	67.05%
Total		**349**	**100.00%**

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or a similar type of disease and the same or similar patient population, the applicant stated that amivantamab treats a distinct patient population with metastatic NSCLC: Metastatic NSCLC with exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. Per the applicant, there is currently no FDA-approved therapy for this patient population, and the most commonly used therapies are associated with limited efficacy.

In summary, the applicant asserted that amivantamab should be considered new and not substantially similar to an existing technology because the mechanism of action of amivantamab for treating NSCLC is unique and it treats a distinct patient population.

We are inviting public comments on whether amivantamab is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2019 Medicare Provider Analysis and Review (MedPAR) final rule file for cases based on the presence of one of the following ICD–10–CM diagnosis codes for lung cancer:

Code	Code Descriptor
C34	Malignant neoplasm of bronchus and lung
C34.0	Malignant neoplasm of main bronchus
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	Malignant neoplasm of upper lobe, bronchus or lung
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	Malignant neoplasm of unspecified part of bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

We note that the applicant also provided the following ICD–10–PCS procedure codes, which the applicant stated could be used to identify cases involving amivantamab in the absence of a unique ICD–10–PCS code.

Code	Code Descriptor
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

To further refine the cases used in the analysis, the applicant used the following methodology. Per the applicant, clinical data suggests 80 to 85 percent of lung cancer patients are NSCLC patients.[30] The applicant stated that, of those patients, 10–15 percent are EGFR-mutations patients,[31] [32] and of those, at least 9 percent have atypical EGFR mutations like exon 20 ins.[33] The applicant selected 0.93% (82.5% * 12.5% * 9%) of the cases identified based on the lung cancer diagnosis codes listed previously. The applicant stated this is the target population for amivantamab, which the applicant used for the cost analysis.

The applicant then accounted for the circumstances where amivantamab would be administered during an inpatient stay. The applicant stated that amivantamab will typically be administered in the outpatient setting, and that it assumed that amivantamab would be administered during an inpatient stay, possibly for care unrelated to a patient's cancer treatment, when that stay coincided with the 2-week cycle during which a patient receiving amivantamab would undergo an infusion in the outpatient setting were it not for their inpatient admission. The applicant stated that, because it is very important that patients receive continuity of cancer care, it assumed that some patients would receive their amivantamab infusion during their hospital stay. To account for this scenario, the applicant calculated the average length of stay for all of the cases in its patient population, which it asserted was about 5.862 days. The applicant then divided the average length of stay for all of the cases by 14, as per the applicant amivantamab is administered on 28-day cycle, with a weekly administration for the first cycle, and an administration every 2 weeks thereafter.

The applicant stated that current clinical guidelines are expected to give medical professionals discretion to administer amivantamab during the hospitalization or pause the treatment cycle. To account for physician discretion, the applicant included only 50 percent of these cases in the final cost analysis.

The applicant identified 349 cases mapping to the following MS–DRGs. The applicant has not made a request for amivantamab to map to a new or different MS–DRG for FY 2022.

MS-DRG	MS-DRG Description	Cases
871	Septicemia Or Severe Sepsis w/o Mv >96 Hours w MCC	46
180	Respiratory Neoplasms w MCC	26
164	Major Chest Procedures w CC	17
193	Simple Pneumonia & Pleurisy w MCCW Mcc	14
181	Respiratory Neoplasms w CC	12
	All Other	234
Total		**349**

The applicant assumed patients receiving amivantamab would receive one dose of the drug during their inpatient stay. Because amivantamab would be administered in addition to any other drugs the patient was receiving during their inpatient admission, the applicant did not remove costs associated with any previous technology. The applicant then standardized the charges using the FY 2019 IPPS/LTCH PPS final rule Impact file. Then the applicant applied the 2-year inflation factor of 13.2 percent (1.13218) from the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039). The applicant then added charges for amivantamab, which the applicant determined using the inverse of the FY 2021 IPPS/LTCH PPS final rule pharmacy national average cost to charge ratio (CCR) of 0.187 (85 FR 58601).

Because the applicant calculated a final inflated average case-weighted standardized charge per case of $108,159, which exceeds the case weighted threshold of $64,736, the applicant maintains the technology meets the cost criterion.

Based on the information provided by the applicant, we have several concerns with regard to whether the technology meets the cost criterion. In its cost analysis, the applicant combined 234 cases from multiple MS–DRGs into one group with a case-weight of 67 percent of cases. We do not believe this is appropriate for the cost analysis. As reflected in § 412.87(b)(3), where cases eligible for a particular technology may be assigned to multiple MS–DRGs, in performing the cost analysis, the applicant should compare the charges of the cases to a threshold amount that is the lesser of 75 percent of the standardized amount or 75 percent of one standard deviation beyond the case-weighted average of all MS–DRGs to which the cases map. In the event that a single MS–DRG has fewer than 11 cases, the applicant should impute a minimum case number of 11 rather than the actual value. In this way, the appropriate threshold and case weighted threshold value can be calculated.

[30] ''What is Lung Cancer?'' American Cancer Society. 1 October 2019: *https://www.cancer.org/content/cancer/en/cancer/lung- cancer/about/what-is.html*.

[31] Wee, P., & Wang, Z. (2017). Epidermal growth factor receptor cell proliferation signaling pathways. *Cancers,* 9(5), 52.

[32] Pao, W., & Girard, N. (2011). New driver mutations in non-small-cell lung cancer. *The Lancet Oncology,* 12(2), 175–180.

[33] Arcila, M. E., Nafa, K., Chaft, J. E., Rekhtman, N., Lau, C., Reva, B. A., and Ladanyi, M. (2013). EGFR exon 20 insertion mutations in lung adenocarcinomas: Prevalence, molecular heterogeneity, and clinicopathologic characteristics. *Molecular Cancer Therapeutics,* 12(2), 220–229.

In its analysis, the applicant appears to take a sample of a larger case population based on clinical data. It is unclear whether the applicant is taking a simple random sample or a targeted sample of cases. We note that, if the applicant obtained a random sample, this sample may not be any more representative of the larger population of cases identified by the lung cancer diagnosis codes listed previously. If the applicant instead non-randomly sampled cases from the larger population, we would like to understand the process used by the applicant to identify this targeted sample. Under either approach, we would request information on how a sampling of cases from the greater population is more representative of potential amivantamab patients.

We are inviting public comments on whether amivantamab meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that amivantamab represents a substantial clinical improvement over existing technologies. The applicant asserted several claims of substantial clinical improvement for amivantamab: (1) Amivantamab is anticipated to be the first therapy to treat the metastatic NSCLC with exon 20 insertion mutations for patients whose disease has progressed on or after platinum-based chemotherapy; (2) the objective response rate (ORR) was higher than what would be expected with chemotherapy or immunotherapy; (3) a clinical benefit rate higher than what would be expected with chemotherapy or immunotherapy; (4) a duration of response higher than what would be expected with chemotherapy or immunotherapy; (5) the median progression free survival was higher than what would be expected with chemotherapy or immunotherapy; and (6) the incidence and severity of diarrhea was lower than what would be expected with any oral EGFR inhibitor.

The applicant stated that patients with NSCLC and EGFR exon 20 insertion mutations have a form of disease that is generally insensitive to available EGFR TKI treatments and, as a result, carries a worse prognosis compared to patients with more common EGFR mutations.[34] Per the applicant, the current standard of care for the initial treatment of exon 20 insertion metastatic NSCLC is platinum-based chemotherapy;[35] and, after a patient with EGFR exon 20 insertion metastatic NSCLC disease progresses on or during platinum-based chemotherapy, there is no standard of care. The applicant stated there are currently no FDA-approved targeted therapies for patients with lung cancer who have EGFR exon 20 insertion mutations.[36] The applicant cited an analysis of the Flatiron Health database, which includes electronic health data records from over 265 cancer clinics representing over 2 million active US cancer patients, that found prescribers use a wide variety of treatment strategies, all of which have an unclear role in the second-line treatment of exon 20 insertion mutated metastatic NSCLC or are known to be ineffective and/or have potential tolerability issues.[37] Specifically, the analysis showed that in the second-line treatment of exon 20 insertion metastatic NSCLC, approximately 33 percent of patients received single-agent immunotherapy, 14.1 percent received an EGFR-targeting oral agent, 5.9 percent received chemoimmunotherapy combination, 5.9 percent received chemotherapy with a VEGF inhibitor, 5.9 percent received a clinical study drug, and the remainder received a variety of single-agent chemotherapies or other regimens. The applicant stated this re-iterates the lack of an accepted standard of care for the second-line treatment of exon 20 insertion metastatic NSCLC and thus underscores the unmet need of these patients. According to the applicant, based on the Breakthrough Therapy designation for amivantamab, it is anticipated that amivantamab's first expected approval will be for the second-line treatment of exon 20 insertion metastatic NSCLC.

The applicant provided three references to support a finding of substantial clinical improvement for amivantamab as well as some supplementary information in the application itself. The first reference was a conference presentation given at the 2019 Annual Meeting of the Society for Clinical Oncology titled ''JNJ–61186372 (JNJ–372), an EGFR-cMet bispecific antibody, in EGFR-driven advanced non-small cell lung cancer (NSCLC)'' by Haura et al. The second was a poster presented at the 2020 Annual Meeting of the American Society for Clinical Oncology titled ''Amivantamab (JNJ–61186372), an anti-EGFR–MET bispecific antibody, in patients with EGFR Exon 20 insertion (Exon20ins)-mutated non-small cell lung cancer (NSCLC)'' by Park et al. The third was a conference presentation given in January 2021 at the World Conference on Lung Cancer titled ''Amivantamab in Post-platinum EGFR Exon 20 Insertion Mutant Non-small Cell Lung Cancer'' by Sabari et al.

These three references all describe the ongoing Phase 1 trial titled ''A Phase 1, First-in-Human, Open-Label, Dose Escalation Study of JNJ–61186372, a Human Bispecific EGFR and cMet Antibody, in Subjects With Advanced Non-Small Cell Lung Cancer'' (*https://clinicaltrials.gov/ct2/show/NCT02609776*). This open label, multicenter, first-in-human study, also known as ''CHRYSALIS,'' consists of two parts.[38] Part 1 was a dose escalation study used to establish the recommended Phase 2 dosing regimen.[39] Part 2 was a dose expansion study to assess safety and efficacy at the recommended Phase 2 dosing regimen.[40] The primary efficacy endpoint was the overall response rate per Response Evaluation Criteria in Solid Tumors v1.1.[41] Key secondary endpoints included clinical benefit rate (CBR), duration of response (DOR), progression-free survival (PFS), and overall survival (OS).[42]

Key eligibility criteria for the post-platinum population of patients enrolled in the study included: Metastatic/unresectable NSCLC, EGFR exon 20 insertion mutation, and progression on platinum-based chemotherapy.[43] Patients received the recommended Phase 2 dose of 1050 mg (1400 mg for patients ≥80 kg) amivantamab intravenously once weekly for the first cycle and biweekly thereafter.[44] The safety population

[34] Vyse, S., and Huang, P. H. (2019). Targeting EGFR exon 20 insertion mutations in non-small cell lung cancer. *Signal Transduction and Targeted Therapy,* 4(1), 1–10.

[35] Chantharasamee, J., Poungvarin, N., Danchaivijitr, P., and Techawatanawanna, S. (2019). Clinical outcome of treatment of metastatic non-small cell lung cancer in patients harboring uncommon EGFR mutation. *BMC Cancer,* 19(1), 701.

[36] Yasuda, H., Kobayashi, S., and Costa, D. B. (2012). EGFR exon 20 insertion mutations in non-small-cell lung cancer: Preclinical data and clinical implications. *The Lancet Oncology,* 13(1), e23–e31.

[37] Flatiron Health database, Second Line Treatment Regimens in Advanced NSCLC (January 2015–October 2019).

[38] *https://clinicaltrials.gov/ct2/show/study/NCT02609776 https://clinicaltrials.gov/ct2/show/study/NCT02609776*

[39] Sabari JK, Shu CA, Park K, et al. Amivantamab in post-platinum EGFR exon 20 insertion mutant non-small cell lung cancer. Oral presentation presented at: International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer Singapore (WCLC 2020); January 28–31, 2021; Worldwide Virtual Event.

[40] Ibid.

[41] Ibid.

[42] Ibid.

[43] Ibid.

[44] Ibid.

(N=114) included all post-platinum exon 20 ins patients who received amivantamab at the recommended Phase 2 dose, and the response-evaluable population (n=81) included post-platinum exon 20 ins patients who had at least three disease assessments or had discontinued, progressed, or died prior to the third post-baseline assessment at the time of clinical cut-off.[45]

In the efficacy population, the median age was 62.[46] In addition, 59 percent of the patients were female, 49 percent of the patients were Asian, and 47 percent had a history of smoking.[47] Median time from initial diagnosis was 17 months with a range of 1–130 months.[48] All patients, by definition, had a prior history of platinum-based chemotherapy while 46 percent had prior immuno-oncology therapy and 25 percent had a history of EGFR TKI treatment.[49]

In the safety population, 98 percent of patients experienced a treatment-related adverse event.[50] Of these, 16 percent were Grade 3 or higher, 9 percent were serious, 4 percent led to discontinuation, 13 percent led to dose reduction, and 21 percent led to dose interruption.[51] Of note, 2 percent discontinued due to rash and 10 percent had treatment-related diarrhea with 8.5 percent at grade 1–2 and 3.5 percent at grade 3.[52]

The applicant stated that preliminary safety results from the CHRYSALIS trial presented at the 2020 ASCO meeting appear to demonstrate that amivantamab has a manageable safety profile, with 60% of adverse events at grade 1 to 2.[53] Per the applicant, this appears to be an improvement relative to the types and frequency of adverse events reported for platinum based chemotherapies overall in advanced NSCLC, with over half of patients reporting adverse events of grade 3 to 5, such as neutropenia, nausea, and vomiting.[54] The applicant noted the best tolerated EGFR-targeting oral agent osimertinib was associated with a rate of discontinuation due to adverse events of 13 percent in the phase 3 FLAURA study.[55] In addition, the applicant noted osimertinib was associated with a rate of any grade diarrhea of 58 percent with 2 percent of patients having grade 3 or higher in this study.[56] In the same phase 3 FLAURA study, the applicant noted the comparator arm (gefitinib or erlotinib) was associated with a 57 percent incidence of any grade diarrhea with 2 percent of patients experiencing grade 3 or higher.

Regarding efficacy, in the Sabari et al reference, a blinded independent central review found an ORR in the efficacy population of 40 percent (95 percent CI 29–51) and a median DOR of 11.1 months (95 percent CI 6.9-not reached).[57] Patients experienced a complete response in 4 percent of cases, partial response in 36 percent of cases, stable disease in 48 percent of cases, progressive disease in 10 percent of cases, and one percent of patients was not evaluable.[58] Finally, the CBR (defined as complete response, partial response, or stable disease for at least two disease assessments) was 74 percent (95 percent CI 63–83).[59] The median patient follow-up in this most recent analysis was 9.7 months (range 1.1–29.3). Of note, 47 percent of patients remained on treatment at time of data cutoff and 63 percent had responses of at least six months.[60] The median PFS was 8.3 months (95 percent CI 6.5–10.9), and the median overall survival was 22.8 months (95 percent CI 14.6-not reached).[61]

The applicant stated that, while direct comparison between therapies cannot be definitively made in the absence of comparative trials, amivantamab results appear promising and numerically better than those expected with current therapies (chemotherapy, immunotherapy, chemoimmunotherapy combination, or oral EGFR tyrosine kinase inhibitors) based on available data. The applicant stated platinum-based chemotherapy has been associated with a median progression free survival of 5.1 to 6.0 months in patients with exon 20 T790m mutations–the most common mutation observed following resistance to small molecule TKI inhibitors commonly used in advanced EGFR mutation positive NSCLC.[62] The applicant stated that oral EGFR tyrosine kinase inhibitors (for example, erlotinib, gefitinib, afatinib, dacomitinib, osimertinib) and immunotherapies are also used to treat patients with exon 20 insertion metastatic NSCLC but generally have limited efficacy as exon 20 insertion mutations have been associated with resistance to EGFR tyrosine kinase inhibitors.[63] The applicant stated most immunotherapy and chemoimmunotherapy studies have excluded patients with EGFR mutation because single-agent immunotherapies have very limited efficacy in patients with EGFR-mutated NSCLC.

The applicant provided the following table 1, which outlines median progression free survival (mPFS) and response rate (ORR) data among patients with exon 20 insertion mutation for amivantamab and some of the currently existing therapies. The applicant noted this table is intended to provide general information about individual therapies and is not intended for making direct comparisons between therapies as differences between study populations, follow-up time, prior treatments, and other factors may exist.

	Chemotherapy	Afatinib	Osimertinib	Erlotinib/Gefitinib	Amivantamab
mPFS	5.7 months	2.7 months	3.7 months	< 3 months	8.6 months
ORR	29%	9%	6%	8% - 27%	41%

Sources: Exon 20 - Chemotherapy: Zhao et al. WCLC 2018; Afatinib: Yang et al. Lancet Oncol. 2015; Osimertinib: de Langen et al. WCLC 2018; Erlotinib/Gefitinb: Vyse et al. STTT 2019; Amivantamab: Park et al. ASCO 2020.

[45] Ibid.

[46] Ibid.

[47] Ibid.

[48] Ibid.

[49] Ibid.

[50] Ibid.

[51] Ibid.

[52] Ibid.

[53] 2020 ASCO Annual Meeting: Park, K, et al. J Clin Oncol 38:2020 (suppl; abstr 9512).

[54] Schiller, JH et al. (2002). Comparison of four chemotherapy regimens for advanced non–small-cell lung cancer. *New England Journal of Medicine,* 346(2), 92–98.

[55] Ibid.

[56] Ibid.

[57] Sabari JK, Shu CA, Park K, et al. Amivantamab in post-platinum EGFR exon 20 insertion mutant non-small cell lung cancer. Oral presentation presented at: International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer Singapore (WCLC 2020); January 28–31, 2021; Worldwide Virtual Event.

[58] Ibid.

[59] Ibid.

[60] Ibid.

[61] Ibid.

[62] Yoshida, T., Kuroda, H., Oya, Y., Shimizu, J., Horio, Y., Sakao, Y., et al. . . . and Yatabe, Y. (2017). Clinical outcomes of platinum-based chemotherapy according to T790M mutation status in EGFR-positive non-small cell lung cancer patients after initial EGFR–TKI failure. Lung Cancer, 109, 89–91.

[63] Vyse, S., & Huang, P. H. (2019). Targeting EGFR exon 20 insertion mutations in non-small cell lung cancer. *Signal Transduction and Targeted Therapy,* 4(1), 1–10.

Finally, the applicant cited an analysis presented at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, which found patients experienced a median ORR of 13% and PFS of 3.5 months when receiving a wide variety of different therapies, including immunotherapies, chemoimmunotherapies, EGFR-targeting TKIs, and other chemotherapy regimens as second-line treatment.[64]

After review of the information provided by the applicant, we have the following concerns regarding whether the technology meets the substantial clinical improvement criterion. Currently, results provided by the applicant are based on an ongoing Phase 1 trial. We are concerned that these are potentially partial results, from which end conclusions may not be drawn, and also about the potential for overestimating treatment effects when trials stop early or report interim results. We further note that the only study cited by the application to establish substantial clinical improvement is a single-armed study assessing the safety and efficacy of amivantamab in the target population. As noted by the applicant, no formal comparisons to other therapies have been made. Without the ability to control for factors such as study design, patient characteristics, etc., we may be unable to determine whether any differences seen are the result of amivantamab's potentially superior efficacy or confounding variables. We also note that the single-arm study design results in an inability to distinguish between the effect of amivantamab treatment, a placebo effect, and the effect of natural course of the disease.

We are inviting public comments on whether amivantamab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for amivantamab.

c. Breyanzi® (lisocabtagene maraleucel)

Juno Therapeutics, a Bristol-Myers Squibb Company, submitted an application for new technology add-on payment for FY 2022 for Breyanzi®. Breyanzi® is a CD19-directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy that is comprised of individually formulated CD8 (killer) and CD4 (helper) CAR T-cells indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after at least two prior therapies. We note that Juno Therapeutics previously submitted an application for new technology add-on payments for Breyanzi® for FY 2021, as summarized in the FY 2021 IPPS/LTCH PPS proposed rule, under the name lisocabtagene maraleucel (85 FR 32647–32652).

According to the National Comprehensive Cancer Network, Diffuse Large B-cell lymphoma (DLBCL) is the most common type of Non-Hodgkin's Lymphoma (NHL) in the U.S. and worldwide, accounting for nearly 30% of newly diagnosed cases of B-cell NHL in U.S.[65] DLBCL is characterized by spreading of B-cells through the body that have either arrived de novo or by the transformation from indolent lymphoma.

According to the applicant, the standard-of-care, first-line immune-chemotherapy for DLBCL includes regimens such as cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab (R–CHOP).[66] These regimens result in long-lasting remission in more than 50% of patients.[67] However, approximately 10% to 15% of patients will have primary refractory disease (that is, nonresponse or relapse within 3 months of first-line therapy), and an additional 20% to 25% will relapse following an initial response to therapy.[68] Patients with relapses of aggressive B-cell lymphomas are believed to have a poor prognosis because of potential treatment resistance and rapid tumor growth, with only about 30% to 40% responding to salvage chemotherapy (for example, R–ICE, DHAP, or Gem-ox) followed by high-dose therapy and autologous stem cell transplantation for patients demonstrating chemotherapy-sensitive disease.[69] [70] Among patients eligible to undergo autologous stem cell transplantation (ASCT), only 50% will achieve a remission adequate to proceed to ASCT, and approximately 50% will relapse after transplantation.[71] The applicant also noted that transplant eligibility is also restricted based on age and tolerance to high dose chemotherapy and thus excludes a moderate subset of patients with r/r DLBCL.

Additionally, the applicant explained that the available therapies for 3L+ large B-cell lymphoma include the following:

- CD19-directed genetically modified autologous CAR T-cell immunotherapy axicabtagene ciloleucel (YESCARTA®), approved in October 2017 for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL).[72]
- CAR T-cell therapy tisagenlecluecel (KYMRIAH®), approved in May 2018, for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from FL.[73]
- Programmed death receptor-1 (PD–1)-blocking antibody (KEYTRUDA®), approved in 2018, for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.[74]
- CD79b-directed antibody-drug conjugate polatuzumab vedotin (POLIVY®), in combination with bendamustine and rituximab, approved in 2019, for the treatment of adult patients with r/r DLBCL, not otherwise specified, after at least two prior therapies.

[64] Park, K. (2020, May). Amivantamab (JNJ–61186372), an anti-EGFR–MET bispecific antibody, in patients with EGFR Exon 20 insertion (Exon20ins)-mutated non-small cell lung cancer (NSCLC). Poster presented at the 2020 Annual Meeting of the American Society of Clinical Oncology.

[65] Ferlay J, Colombet M, Soerjomataram, et al., Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods, Int J Cancer. 144: 1941–1953 (Ferlay, 2019); NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V. 5.2019. © National Comprehensive Cancer Network, Inc. 2019 (NCCN, 2019).

[66] Coiffier, BBertrand et. al, Long-term outcome of patients in the LNH–98.5 trial, the first randomized study comparing rituximab-CHOP to standard CHOP chemotherapy in DLBCL patients: a study by Group d'Etudes des Lymphomes de l'Adulte, blood 2010 116: 2040–2045. (Coiffier, 2010).

[67] *Ibid*

[68] Ibid

[69] Crump M, Neelapu SS, Farooq U, et al., Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study, Blood. 2017; 130(16): 1800–1808 (Crump, 2017).);

[70] Cunningham D, Hawkes EA, Jack A, et al. Rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisolone in patients with newly diagnosed diffuse large B-cell non-Hodgkin lymphoma: a phase 3 comparison of dose intensification with 14-day versus 21-day cycles Lancet. 2013; 381: 1817–1826 (Cunningham, 2013).

[71] *Ibid*

[72] YESCARTA®'s approval was based on a single arm study (ZUMA–1) demonstrating an IRC-assessed ORR of 72%, CR of 51%, and an estimated median DOR of 9.2 months in 101 subjects included in the modified intent-to-treat (mITT population).

[73] KYMRIAH®'s approval was based on a single-arm study (JULIET) demonstrating an ORR of 50% and a CR rate of 32% in 68 efficacy-evaluable subjects. A median DOR was not reached with a median follow-up of 9.4 months.

[74] KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy. Keytruda USPI (2019).

According to the applicant, despite the availability of these therapies, r/r large B-cell lymphoma remains a major cause of morbidity and mortality due to the aggressive disease course. The applicant noted that the safety profiles of these therapies exclude many r/r large B-cell lymphoma patients from being able to undergo treatment with these therapies.[75]

With respect to the newness criterion, the applicant submitted a BLA for Breyanzi® in October 2019, and was approved by FDA on February 5, 2021. Breyanzi® was granted Breakthrough Therapy Designation (BTD) on December 15, 2016 and Regenerative Medicine Advanced Therapy (RMAT) designation on October 20, 2017, for the treatment of patients with r/r aggressive large B-cell NHL, including DLBCL, not otherwise specified (DLBCL NOS; de novo or transformed from indolent lymphoma), primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma Grade 3B (FL3B)). Breyanzi® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. Breyanzi® is not indicated for the treatment of patients with primary central nervous system lymphoma. We note that effective October 1, 2021 the following ICD–10–PCS codes may be used to uniquely describe procedures involving the infusion of Breyanzi®: XW033N7 (Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043N7 (Introduction of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7). The applicant also submitted a request for a new HCPCS code, which will uniquely describe procedures involving the use of Breyanzi®. The applicant noted in their application that Breyanzi® would likely map to the same MS–DRG as other CAR T-cell therapies, MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy).

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant described two ways in which it believes the mechanism of action for Breyanzi® differs from previously approved therapies for DLBCL. First, the applicant described the therapy as being comprised of individually formulated cryopreserved patient-specific helper (CD4) and killer (CD8) CAR T-cells in suspension that are administered as a defined composition of CAR-positive viable T-cells (from individually formulated CD8 and CD4 components). The applicant stated that the therapy involves a different mechanism of action from other CAR–T cell therapies because the CD4 and CD8 T-cells are purified and cultured separately to maintain compositional control of each cell type. Furthermore, during culture, each cell type is separately modified to have the CAR on the cell surface, expanded and quantified, and frozen in two separate cell suspensions. The applicant then described how Breyanzi® is infused with the same target dose of CD4 and CD8 CAR T-cells for every patient. The applicant asserted that because Breyanzi® controls the same dosage for both CD4 and CD8, it differs from other CAR T-cell therapies for DLBCL and could potentially provide for higher safety and efficacy; the applicant stated that CAR T-cell therapies that do not control for CD8 CAR T-cell dosage have demonstrated higher rates of severe and life-threatening toxicities, such as cytokine release syndrome (CRS) and neurotoxicity (NT).

The second feature the applicant described as distinguishing Breyanzi®'s mechanism of action from existing CD19-directed CAR T-cell therapies was the presence of an EGFRt cell surface tag. The applicant explained that the EGFRt cell surface tag could hypothetically be targeted for CAR T-cell clearance by separately administering cetuximab, a monoclonal antibody. According to the applicant, if the patient was separately administered cetuximab, the presence of the EGFRt cell surface tag within Breyanzi® would allow cetuximba to bind to the CAR T-cells and clear the cells from the patient. The applicant highlighted studies that showed that persistent functional CD19-directed CAR T-cells in patients caused sustained depletion of a patient's normal B-cells that expressed CD19, resulting in hypogammaglobulinemia and an increased risk of life-threatening or chronic infections.[76] The applicant further explained that such prolonged low levels of normal B-cells could place a patient at risk of life-threatening or chronic infections. According to the applicant, the ability to deplete CAR T-cells, via the administration of cetuximab, when a patient achieves a long-term remission could hypothetically allow recovery of normal B-cells and potentially reduce the risk of life-threatening or chronic infections. The applicant noted that experiments in a laboratory setting showed that targeting EGFRt with the monoclonal antibody cetuximab eliminated CAR T-cells expressing the EGFRt marker, which resulted in long-term reversal of B-cell aplasia in mice.[77] However, the applicant noted that this mechanism of CAR T-cell clearance, via administration of cetuximab and EGFRt cell surface tags/markers, has not been tested in humans, including patients treated with Breyanzi®.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant acknowledged that the ICD–10–PCS procedure codes used to uniquely identify procedures involving the administration of Breyanzi® XW033N7 (Introduction of lisocabtagene maraleucel Immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043N7 (Introduction of lisocabtagene maraleucel Immunotherapy into central vein, percutaneous approach, new technology group 7) are assigned to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). The applicant has not made a request for the technology to map to a new or different MS–DRG for FY 2022.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, Breyanzi® fills an unmet need in the treatment of large B-cell lymphoma because Breyanzi® would be indicated as a third-line treatment option for patients with r/r DLBCL, who cannot be treated with existing CAR T-

[75] Smith SD, Reddy P, Sokolova A, et al., Eligibility for CAR T-cell therapy: An analysis of selection criteria and survival outcomes in chemorefractory DLBCL, Am. J. Hematol. 2019; E119: 1–4 (Smith, 2019).

[76] Kalos M, Levine BL, Porter DL, et al., T Cells with Chimeric Antigen Receptors Have Potent Antitumor Effects and Can Establish Memory in Patients with Advanced Leukemia, Sci Transl Med. 2011; 3(95): 1–21 (Kalos, 2011).

[77] Paszkiewicz PJ, Frable SP, Srivastava S, et al., Targeted antibody-mediated depletion of murine CD19 CAR T cells permanently reverses B cell aplasia, J Clin Invest. 2016; 126(11): 4262–4272 (Paszkiewicz, 2016).

cell therapies. The applicant asserted that Breyanzi® would be able to treat these patients that present with uncommon subtypes of DLBCL including, PMBCL, FL3B, and DLBCL transformed from indolent lymphoma from other follicular lymphoma, elderly patients (≥ 65 years old), patients with secondary CNS involvement by lymphoma, and those with moderate renal or cardiac comorbidities. The applicant asserted that these patient populations were excluded from registrational trials for YESCARTA® and KYMRIAH®, and therefore represent an unmet patient need.

Regarding newness, we are concerned whether a differing production and/or dosage represents a different mechanism of action as compared to previously FDA-approved CAR T-cell therapies. We are also concerned about whether the existence of an EGFRt cell surface tag equates to a new mechanism of action given that in order to activate this cell surface tag, an additional medication, cetuximab, which targets the CAR T-cells for clearance, would be needed. We also express concern that, based on our understanding, the presence of the EGFRt cell surface tag is a potential way to treat an adverse event of the Breyanzi® therapy and is not critical to the way the drug treats the underlying disease. We note that the applicant referenced that while this EGFRt cell surface tag is included within the Breyanzi® compound, it remains dormant without activation by cetuximab. Finally, the applicant noted that Breyanzi® has been shown safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®, including patients with uncommon subtypes of large B-cell lymphoma, including PMBCL, FL3B, and DLBCL transformed from indolent lymphoma other than FL, elderly patients (≥ 65 years old), patients with secondary CNS involvement by lymphoma and those with moderate renal or cardiac comorbidities.[78] We note that the FDA label for YESCARTA® and KYMRIAH® does not appear to specifically exclude these patient populations or NHL subtypes. As such, it is unclear whether Breyanzi® would in fact treat a patient population different from other CAR T-cell therapies that treat patients with DLBCL.

We are inviting public comments on whether Breyanzi® is substantially similar to other technologies and whether Breyanzi® meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR correction notice (December 1, 2020) data file to identify potential cases representing patients who may be eligible for treatment using Breyanzi®. The applicant identified claims that reported an ICD–10–CM diagnosis code of: C83.30 (DLBCL, unspecified site); C83.31 (DLBCL, lymph nodes of head, face and neck); C83.32 (DLBCL, intrathoracic lymph nodes); C83.33 (DLBCL, intra-abdominal lymph nodes); C83.34 (DLBCL, lymph nodes of axilla and upper limb); C83.35 (DLBCL, lymph nodes of inquinal region and lower limb); C83.36 (DLBCL, intrapelvic lymph nodes); C83.37 (DLBCL, spleen); or C83.38 (DLBCL, lymph nodes of multiple sites) in one of the first five diagnosis code positions on the claim. The applicant excluded claims if they had one or more diagnoses from the list below because these conditions would preclude use of Breyanzi®.

BILLING CODE 4120–01–P

ICD-10-CM Code	Code Description
C72	Malignant neoplasm of spinal cord, cranial nerves and other parts of central nervous system
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.2	Malignant neoplasm of olfactory nerve
C72.20	Malignant neoplasm of unspecified olfactory nerve
C72.21	Malignant neoplasm of right olfactory nerve
C72.22	Malignant neoplasm of left olfactory nerve

[78] Lisocabtagene maraleucel Biologics License Application (BLA).

ICD-10-CM Code	Code Description
C72.3	Malignant neoplasm of optic nerve
C72.30	Malignant neoplasm of unspecified optic nerve
C72.31	Malignant neoplasm of right optic nerve
C72.32	Malignant neoplasm of left optic nerve
C72.4	Malignant neoplasm of acoustic nerve
C72.40	Malignant neoplasm of unspecified acoustic nerve
C72.41	Malignant neoplasm of right acoustic nerve
C72.42	Malignant neoplasm of left acoustic nerve
C72.5	Malignant neoplasm of other and unspecified cranial nerves
C72.50	Malignant neoplasm of unspecified cranial nerve
C72.59	Malignant neoplasm of other cranial nerves
C72.9	Malignant neoplasm of central nervous system, unspecified
G40-G40.919	Epilepsy and recurrent seizures
A52.17	General paresis
R47.01	Aphasia
S06-S06.9X9S	Intracranial injury
G20	Parkinson's disease
G32.81	Cerebellar ataxia in diseases classified elsewhere
G11	Hereditary ataxia
G11.0	Congenital nonprogressive ataxia
G11.1	Early-onset cerebellar ataxia
G11.2	Late-onset cerebellar ataxia
G11.3	Cerebellar ataxia with defective DNA repair
G11.4	Hereditary spastic paraplegia
G11.8	Other hereditary ataxias
G11.9	Hereditary ataxia, unspecified
I60-I99	Cerebrovascular diseases
F01-F99	Mental, Behavioral and Neurodevelopmental disorders
C88	Malignant immunoproliferative diseases and certain other B-cell lymphomas
C88.0	Waldenstrom macroglobulinemia
C90	Multiple myeloma and malignant plasma cell neoplasms
C90.1	Plasma cell leukemia

ICD-10-CM Code	Code Description
C90.11	Plasma cell leukemia in remission
C90.12	Plasma cell leukemia in relapse
C90.10	Plasma cell leukemia not having achieved remission
C91	Lymphoid leukemia
C91.5	Adult T-cell lymphoma/leukemia (HTLV-1-associated)
D47	Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
E31	Polyglandular dysfunction
E31.9	Polyglandular dysfunction, unspecified
G61	Inflammatory polyneuropathy
G61.9	Inflammatory polyneuropathy, unspecified
G62	Other and unspecified polyneuropathies
G62.1	Alcoholic polyneuropathy
G62.8	Other specified polyneuropathies
G62.82	Radiation-induced polyneuropathy
G62.81	Critical illness polyneuropathy

BILLING CODE 4120–01–C

However, the applicant noted that the aforementioned C83.XX ICD–10–CM codes do not differentiate r/r patients from the broader DLBCL population. A clinical literature search completed by the applicant found that the r/r population makes up one-fourth of the DLBCL population, but since r/r patients typically have higher inpatient costs the applicant selected 19.36 percent of the cases with the highest total charges for their cost analysis. Applying the previously mentioned parameters, the applicant found a total of 991 cases mapped to 12 MS–DRGs.

The applicant stated that the use of Breyanzi®'s therapy would replace chemotherapy or other drug therapies, including other CAR T-cell therapies. Because of this, the applicant stated they removed all charges in the drug cost center since it was not possible to differentiate between different drugs on inpatient claims. The standardized charges per case were then calculated using the 2019 IPPS/LTCH PPS final rule Impact file and the 2-year inflation factor of 13.2 percent (1.3218) was applied. Finally, to determine the charges for Breyanzi®, the applicant used the inverse of a simulated alternative cost-to-charge ratio (CCR) specifically for CAR T–CELL therapies to account for CAR T-cell therapies' higher costs compared to other drugs. To determine this alternative CCR for CAR T-cell therapies, the applicant referred to the FY 2021 IPPS final rule AOR/BOR file and calculated an alternative markup percentage by dividing the AOR drug charges within MS–DRG 018 by the number of cases to determine a per case drug charge. The applicant then divided the drug charges per case by $373,000, the acquisition cost of YESCARTA and KYMRIAH, the CAR T-cell products used in those claims, to arrive at a CCR of 0.295. The applicant noted that the cost of Breyanzi® had not yet been determined at the time of application. However, for the purposes of its cost analysis, the applicant assumed the per-patient cost to the hospital will be $373,000. Based on the FY 2021 IPPS/LTCH PPS final rule correction notice data file thresholds for FY 2022, the applicant calculated a final inflated average case-weighted standardized charge per case of $1,377,616 which exceeded the MS–DRG 018 average case-weighted threshold of $1,251,127 by $126,489. Therefore, the applicant stated that Breyanzi® met the cost criterion.

As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR, we are uncertain how representative this data is for use in the applicant's cost analyses given this potential for variability.

We continue to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. We welcome comment on this issue.

We invite public comment on whether Breyanzi® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Breyanzi® represents a substantial clinical improvement over existing technologies because: (1) The totality of the circumstances regarding Breyanzi®'s clinical efficacy, safety, and data make clear that Breyanzi® substantially improves, relative to services or technologies previously available, the treatment of Medicare beneficiaries with R/R NHL; (2) Breyanzi® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; (3) Breyanzi® has, overall, an improved safety profile compared to YESCARTA and KYMRIAH; (4) Breyanzi® has a comparable or superior effectiveness compared to existing therapies; and (5) Breyanzi®'s patient population in its registrational study more accurately reflects real-world NHL patients compared to the studies of currently available CAR T-cell therapies.

The applicant asserts that the totality of the clinical efficacy and safety data from the TRANSCEND NHL 001 trial, which is a prospective, single arm, multicenter study of Breyanzi® in patients with r/r aggressive B-cell NHL, and the supportive safety data from the Breyanzi® clinical studies included in their Biologics License Application (BLA) submission demonstrate that Breyanzi® has equal or better efficacy and a better safety profile in a broad R/R patient population that better approximates the real world large B-cell lymphoma patient population—a population that the applicant asserted includes NHL subtypes not studied or approved for treatment with current approved or conditionally approved agents.

The applicant shared the results of the Phase I TRANSCEND NHL 001 trial, which was a prospective, single arm, multicenter study of lisocabtagene maraleucel in patients with relapsed/refractory aggressive B-cell NHL. The applicant noted that TRANSCEND NHL 001 included subjects with the average age of 63 years with 111 subjects (41%) over 65 years of age and 27 (10%) subjects older than 75 years of age. These patients also failed previous therapies. Of the total number of subjects studied (efficacy: n=256; safety: n=269), 137 subjects (51%) had DLBCL, 60 (22%) had DLBCL transformed from FL, 18 (7%) had DLBCL transformed other indolent lymphomas, 36 patients (13%) had high grade lymphoma, 15 (6%) had PMBCL and 3 (1%) had FL3B.[79] Additionally, the applicant explained that TRANSCEND NHL 001 was more inclusive, compared to the registrational trials for KYMRIAH® and YESCARTA®, of Medicare aged patients with comorbidities and NHL disease subtypes seen in the real world presentation of the disease. To support this, the applicant referenced that within this study, between 40% to 50% of subjects studied had cardiac ejection fraction, 3% had secondary CNS lymphoma, 51 patients (19%) had a creatinine clearance between 30–60 mL/min and 39 patients (14.6%) had grade ≥ 3 cytopenias. Furthermore, the applicant noted that 51 patients (19%) had decreased renal function and 13 patients (4.9%) had decreased cardiac function. The applicant stated that the TRANSCEND NHL 001 study showcased that the patient population treated during the study better reflected the real world large B-cell lymphoma patient population, a population that the applicant asserted included NHL subtypes not studied or approved for treatment with currently approved or conditionally approved agents, while providing similar safety and efficacy. The applicant contended that these high-unmet need large B-cell lymphoma subsets included patients with DLBCL transformed from rare indolent lymphomas other than FL, patients with FL3B, patients 65 years of age and older, as well as patients with moderate comorbidities of renal and cardiac insufficiency.

The applicant further explained that Breyanzi® provided improved effectiveness as compared to existing therapies. Patients with aggressive large B-cell NHL who have failed at least 2 prior therapies or SCT are treated with combinations of agents or monotherapy based on institutional preferences, but there is no standard of care for salvage therapies beyond first treatment therapy.[80] The applicant noted that commonly used salvage therapies (non-CAR T-cell therapies) for relapsed, large B-cell lymphoma demonstrated objective response rates (ORRs) in the range of 12% to 46% and complete response (CR) rates of 6% to 38%. Among the patients who did achieve a response, the median duration of response (DOR) ranges from approximately 6 to 17 months and median overall survival was generally less than 12 months.[81 82 83 84 85 86 87] Comparatively, TRANSCEND NHL 001, which provided subjects with Breyanzi®, met its primary endpoint of Independent Review Committee (IRC)-assessed ORR in adult patients with r/r large lymphoma after at least 2 prior therapies, as reported by the applicant. In the 256 efficacy evaluable patients, the ORR was 73% (95% confidence interval (CI): 67.0% to 78.3%), and the CR rate was 53% (95% CI: 46.6% to 59.2%). With a median follow-up of 10.8 months, the median DOR per IRC assessment was 13.3 months and the median DOR for CR was not reached. By comparison, the applicant summarized that YESCARTA®, as demonstrated in the Phase I–II ZUMA–1 study (see the FY 2019 IPPS/LTCH PPS final rule 83 FR 41295 for a description of this study), had an ORR of 72.0% (95% confidence interval (CI: 62.0% to 81.0%)). Also, according to the applicant, KYMRIAH®, as demonstrated by the Phase II JULIET study (see the FY 2019 IPPS/LTCH PPS final rule 83 FR 41293 for a description of this study), had an ORR of 50.0% (95% confidence interval (CI: 38.0% to 62.0%)). The applicant contended that the results for Breyanzi® (ORR of 73% (95% confidence interval (CI): 67.0% to 78.3%), and the CR rate of 53% (95% CI: 46.6% to 59.2%) were observed across all subgroups tested, including

[79] Ibid.

[80] National Comprehensive CancerNetwork Treatment of Cancer: Guidelines, 2019. NCCN, 2019.

[81] Czuczman MS, Davies A, Linton KM, et al., A Phase 2/3 Multicenter, Randomized Study Comparing the Efficacy and Safety of Lenalidomide Versus Investigator's Choice in Relapsed/Refractory DLBCL, Blood. 2014; 124: 628 (Czuczman, 2014).

[82] Jacobsen ED, Sharman JP, Oki Y, et al., Brentuximab vedotin demonstrates objective responses in a phase 2 study of relapsed/refractory DLBCL with variable CD30 expression, Blood. 2015; 125(9): 1394–1402 (Jacobsen, 2015).

[83] Nagle SJ, Woo K, Schuster SJ, et al., Outcomes of patients with relapsed/refractory diffuse large B-cell lymphoma with progression of lymphoma after autologous stem cell transplantation in the rituximab era, Am. J. Hematol. 2013; 88: 890–894 (Nagle, 2013).

[84] Pettengell R, Coiffier B, Narayanan G, et al., Pixantrone dimaleate versus other chemotherapeutic agents as a single-agent salvage treatment in patients with relapsed or refractory aggressive non-Hodgkin lymphoma: a phase 3, multicenter, open-label, randomised trial, Lancet Oncol. 2012; 13: 696–706 (Pettengell, 2012).

[85] Rigacci L, Puccini B, Cortelazzo S, et al., Bendamustine with or without rituximab for the treatment of heavily pretreated non-Hodgkin's lymphoma patients, Ann Hematol. 2012; 91: 1013–1022 (Rigacci, 2012).

[86] Van Den Neste E, Schmitz N, Mounier N, et al., Outcome of patients with relapsed diffuse large B-cell lymphoma who fail second-line salvage regimens in the International CORAL study, Bone Marrow Transplantation. 2016; 51: 51–57 (Van Den Neste, 2016).

[87] Wang M, Fowler N, Wagner-Bartak N, et al., Oral lenalidomide with rituximab in relapsed or refractory diffuse large cell, follicular and transformed lymphoma: a phase II clinical trial, Leukemia. 2013; 27: 1902–1909 (Wang, 2013).

elderly subjects, those with high burden disease or high baseline inflammatory biomarkers, those requiring anti-lymphoma therapy for disease control, as well as rare patient populations with a high unmet medical need (for example, PMBCL, DLBCL transformed from indolent lymphoma other than FL, and FL3B). The applicant contended that this data supports that Breyanzi® demonstrates comparable or superior effectiveness compared to existing therapies for patients with r/r large B-cell NHL.[88] [89]

Furthermore, the applicant stated that Breyanzi® had an improved safety profile in comparison to YESCARTA® and KYMRIAH®. The applicant stated that both of these FDA-approved CAR T-cell therapies had higher rates of toxicity as compared to Breyanzi®. In the TRANSCEND NHL 001 registrational study (n=268), 42% and 2% of subjects developed all-grade and Grade > 3 CRS, respectively, and 30% and 10% developed all-grade and Grade > 3 NT. The applicant compared these results to the results of the JULIET study as found in KYMRIAH's® prescribing information and summarized that KYMRIAH® had higher rates of all-grade and Grade > 3 CRS (74% and 23%, respectively) and all-grade and Grade > 3 NT (58% and 18%, respectively). The applicant provided the same comparison of the toxicity results of Breyanzi® to the results showcased in the ZUMA–1 study featuring YESCARTA® as found in YESCARTA®'s prescribing information and summarized that YESCARTA® had higher rates of all-grade and Grade > 3 CRS (94% and 13%, respectively) and all-grade and Grade > 3 NT (87% and 31%, respectively).[90] [91]

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application, we are concerned that there are no published studies directly comparing Breyanzi® and the two currently available CAR T-cell therapies for r/r DLBCL, YESCARTA® and KYMRIAH®. Additionally, we are concerned with the lack of long-term data supporting the effectiveness and efficacy of Breyanzi® and whether the lack of long-term data may limit the generalizability of the findings from the TRANSCEND NHL 001 study to the general Medicare population. While there have been no direct comparison studies of Breyanzi®, YESCARTA® and KYMRIAH®, the applicant does provide a comparison of the ORR, CR, PR and DOR across all three CAR T-cell therapies. While we note that Breyanzi® does appear to provide an improved ORR, CR, PR, and DOR compared to the other FDA-approved CAR T-cell therapies based on the data presented by the applicant, we further note that these differences appear to be small in magnitude, between 1–2% for the ORR, CR, and PR. Without a direct comparison of outcomes between these therapies, we are concerned as to whether these differences translate to clinically meaningful differences or improvements. Breyanzi® appears to demonstrate similar patient outcomes to that of YESCARTA® and we question whether the TRANSCEND NHL 001 study is evidence that Breyanzi® is a more effective therapy to treat DLBCL over existing CAR T-cell therapies. Additionally, as previously discussed, the applicant noted that Breyanzi® has been shown safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®. However, it is unclear whether this suggests that Breyanzi® is a treatment option for patients who cannot be treated with these existing CAR T-cell therapies, given that the FDA label for YESCARTA® and KYMRIAH® appears to not specifically exclude these patient populations. Finally, we are concerned that the use of the EGFRt cell surface tag was not activated in patients receiving Breyanzi® to study the impact of clearing these CAR T-cells after remission and that this feature has not yet been tested on humans or in conjunction with patients treated with Breyanzi®. We express concern regarding the safety and efficacy of this feature given its lack of testing.

We are inviting public comments on whether Breyanzi® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Breyanzi® or at the New Technology Town Hall meeting.

d. Ciltacabtagene Autoleucel

Janssen Biotech, Inc., submitted an application for new technology add-on payments for ciltacabtagene autoleucel for FY 2022. Ciltacabtagene autoleucel is an autologous chimeric-antigen receptor (CAR) T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma.

Ciltacabtagene autoleucel refers to both JNJ–4528, an investigational BCMA-directed CAR T-cell therapy for previously treated patients with multiple myeloma, and LCAR–B38M, the investigational product (ciltacabtagene autoleucel) being studied in China. Both JNJ–4528 and LACAR–B38M are representative of the same CAR T-cell therapy, ciltacabtagene autoleucel. Ciltacabtagene autoleucel has not yet received FDA approval.

Multiple myeloma (MM) is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. The diagnosis of MM is often suspected because of one (or more) of the following clinical presentations:

- Bone pain with lytic lesions discovered on routine skeletal films or other imaging modalities.
- An increased total serum protein concentration and/or the presence of a monoclonal protein in the urine or serum.
- Systemic signs or symptoms suggestive of malignancy, such as unexplained anemia.
- Hypercalcemia, which is either symptomatic or discovered incidentally.
- Acute renal failure with a bland urinalysis or rarely nephrotic syndrome due to concurrent immunoglobulin light chain (AL) amyloidosis.

It is important to distinguish MM both from other causes of the clinical presentations mentioned previously and from other plasma cell dyscrasias for the purposes of prognosis and treatment.[92] Data from the US Surveillance, Epidemiology, and End Results (SEER) registry estimate 32,000 new cases of MM and 13,000 deaths from MM annually in the U.S. This correlates with an annual incidence of approximately 7 per 100,000 men and women per year. MM is largely a disease of older adults. The median age at diagnosis is 65 to 74 years. MM is also slightly more frequent in men than in women (approximately 1.4:1). MM is associated with substantial morbidity and mortality [93]

[88] YESCARTA® United States Prescribing Information USPI (2019).

[89] KYMRIAH® United States Prescribing Information USPI (2018).

[90] YESCARTA® USPI (2019).

[91] KYMRIAH® USPI (2018).

[92] Laubauch, J.P. (2021). Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. UptoDate. Available from *https://www.uptodate.com/contents/multiple-myeloma-clinical-features-laboratory-manifestations-and diagnosis?search=multiple%20myeloma&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.*

[93] Cowan AJ, Allen C, Barac A, Basaleem H, Bensenor I, Curado MP, Foreman K, Gupta R,

Continued

and approximately 25% of patients have a median survival of 2 years or less.[94]

According to the applicant, introduction of new treatment options in the last 2 decades has extended the median survival of multiple myeloma patients. The applicant asserted that the introduction of proteasome inhibitors (PI) (*e.g.,* bortezomib, carfilzomib, and ixazomib), histone deacetylase inhibitors (*e.g.,* panobinostat, vorinostat), immunomodulatory agents (IMiD) (*e.g.,* thalidomide, lenalidomide, and pomalidomide), monoclonal antibodies (daratumumab and elotuzumab), and stem cell transplantation, have allowed numerous therapeutic options for patients with multiple myeloma (Rajkumar 2020). According to the applicant, the National Comprehensive Cancer Network (NCCN) recommended treatment regimen for first-line therapy of multiple myeloma is Bortezomib (a proteosome inhibitor (PI)), lenalidomide (an immunomodulatory agent (IMiD)) and dexamethasone.[95] The strategy of triplet therapies for patients with newly diagnosed multiple myeloma, followed by high-dose chemotherapy and autologous stem-cell transplantation for eligible patients, and subsequently consolidation and maintenance therapy, is the current treatment roadmap for patients.[96] However, despite these treatments, according to the applicant, most patients will relapse after first-line treatment and require further treatment [97] with only 50% survival of relapsed patients after 5 years.[98] [99] As multiple myeloma progresses, each subsequent line of treatment is associated with shorter progression free survival (PFS) and decreased rate, depth, and durability of response and worsening of quality of life.[100] In addition, cumulative and long-term toxicities are often associated with long-term therapy (Ludwig, 2018). Thus, according to the applicant, there remains an ongoing need for additional therapeutic approaches when the disease is resistant to available therapy.

The applicant asserts that relapsed and refractory multiple myeloma (RRMM) constitutes a specific unmet medical need. According to the applicant, patients with r/r disease are defined as those who, having achieved a minor response or better, relapse and then progress while on therapy, or experience progression within 60 days of their last therapy.[101] The introduction of a new class of agents, CD38-targeting monoclonal antibodies (CD38 MoABs), daratumumab and isatuximab, have improved options in r/r patients.[102] The applicant asserts that given these advances, guideline recommendations following first-line therapy are varied, with treatment options including combinations of novel agents with existing standard of care regimens, and triplet and quadruplet regimens, creating a complex treatment landscape.[103] According to the applicant, while triplet regimens should be used as the standard therapy for patients with multiple myeloma, elderly or frail patients may be treated with double regimens.[104] [95] The applicant further states that for patients with RRMM who have received at least 3 prior lines of therapy including a PI, an IMiD and an anti-CD38, there does not exist a standard or consensus for treatment at this time, and often, supportive care/palliative care is the only option.[105]

According to the applicant, multiple myeloma remains incurable and most patients eventually relapse, even with the advent of new treatments.[106] The applicant further states that novel, innovative therapies are needed to improve long-term survival and outcomes. The applicant asserts that CAR T-cell-based therapies offer potential advantages over current therapeutic strategies. According to the applicant, while other therapies require long-term repetitive administration generally until progression of disease, CAR T-cell therapy is a single infusion treatment due to live T-cell expansion in the patient and long-term disease response. The applicant asserts that ciltacabtagene autoleucel is an autologous CAR T-cell therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma. The applicant states that BCMA, a protein that is highly expressed on myeloma cells [107] and is a member of the tumor necrosis factor (TNF) receptor family, plays a central role in regulating B-cell maturation and differentiation into plasma cells.[108] BCMA is selectively expressed on a subset of B cells (plasma cell neoplasms including myeloma cells) and is more stably expressed specifically on the B cell lineage, compared with key plasma cell marker CD138 which is also expressed on normal fibroblasts and epithelial cells.[109] [110] [111] These expression characteristics, per the applicant, make BCMA an ideal therapeutic target for the treatment of multiple myeloma.[112] [113] Ciltacabtagene autoleucel, according to the applicant, is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

The applicant asserts that CAR T-cell technology is a form of immunotherapy and is a ''living drug'' that utilizes specially altered T cells, part of the immune system, to fight cancer. A

Harvey J, Hosgood HD, Jakovljevic M, Khader Y, Linn S, Lad D, Mantovani L, Nong VM, Mokdad A, Naghavi M, Postma M, Roshandel G, Shackelford K, Sisay M, Nguyen CT, Tran TT, Xuan BT, Ukwaja KN, Vollset SE, Weiderpass E, Libby EN, Fitzmaurice C. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018 Sep 1;4(9):1221–1227.

[94] Biran N, Jagannath S, Chari A. Risk stratification in multiple myeloma, part 1: characterization of high-risk disease. Clin Adv Hematol Oncol. 2013 Aug;11(8):489–503.

[95] National Comprehensive Cancer Network (NCCN) NCCN clinical practice guidelines in oncology. Multiple Myeloma. Version 2. 2021–September 9, 2020.

[96] Branagan A, Lei M, Lou U, Raje N. Current Treatment Strategies for Multiple Myeloma. JCO Oncol Pract. 2020 Jan;16(1):5–14.

[97] Sonneveld P, Broij lA. Treatment of relapsed and refractory multiple myeloma. Haematologica. 2016;101(4):396–406.

[98] SEER database 2020; *https://seer.cancer.gov/statfacts/html/mulmy.html.*

[99] GLOBOCAN database 2018; *https://gco.iarc.fr/today/data/factsheets/populations/900-world-fact-sheets.pdf.*

[100] Yong K, Delforge M, Driessen C, Fink L, Flinois A, Gonzalez-McQuire S, Safaei R, Karlin L, Mateos MV, Raab MS, Schoen P, Cavo M. Multiple myeloma: patient outcomes in real-world practice. Br J Haematol. 2016 Oct;175(2):252–264.

[101] Castelli R, Orofino N, Losurdo A, Gualtierotti R, Cugno M. Choosing treatment options for patients with relapsed/refractory multiple myeloma. Expert Rev Anticancer Ther. 2014 Feb;14(2):199–215.

[102] Van de Donk NWCJ, Richardson PG, Malavasi F. CD38 antibodies in multiple myeloma: back to the future. Blood. 2018 Jan 4;131(1):13–29.

[103] National Comprehensive Cancer Network (NCCN) NCCN clinical practice guidelines in oncology. Multiple Myeloma. Version 2. 2021—September 9, 2020.

[104] Ibid.

[105] Maples KT, Joseph NS, Harvey RD. Current developments in the combination therapy of relapsed/refractory multiple myeloma. Expert Rev Anticancer Ther. 2020 Sep 24.

[106] Rajkumar SV, Kumar S. Multiple myeloma current treatment algorithms. Blood Cancer J. 2020 Sep 28;10(9):94.

[107] Cho SF, Anderson KC, Tai YT. Targeting B Cell Maturation Antigen (BCMA) in Multiple Myeloma: Potential Uses of BCMA-Based Immunotherapy. Front Immunol. 2018 Aug 10;9:1821.

[108] Ibid.

[109] Ibid.

[110] Tai YT, Anderson KC. Targeting B-cell maturation antigen in multiple myeloma. Immunotherapy. 2015;7(11):1187–99.

[111] Palaiologou M, Delladetsima I, Tiniakos D. CD138 (syndecan-1) expression in health and disease. Histol Histopathol. 2014 Feb;29(2):177–89.

[112] Ibid.

[113] Frigyesi I, Adolfsson J, Ali M, Christophersen MK, Johnsson E, Turesson I, Gullberg U, Hansson M, Nilsson B. Robust isolation of malignant plasma cells in multiple myeloma. Blood. 2014 Feb 27;123(9):1336–40.

sample of the patient's T cells are collected from the blood, then modified in a laboratory setting to express a chimeric antigen receptor (CAR).[114] Chimeric antigen receptors are specifically designed receptor proteins that are made up of three distinct features: (1) A target recognition domain (typically derived from a single domain of an antibody) that sits on the cell's exterior, (2) a co-stimulatory domain on the cell's interior that boosts activation, enhances survival and expansion of the modified cells, and (3) an interior stimulatory domain that supports activation and target killing.[115] The binding domain expressed on the surface of T cells gives them the new ability to target a specific protein. When the target is recognized, the intracellular portions of the receptor send signals within the T cells to destroy the target cells. These engineered CAR T-cells are reinfused back into the same patient which enables these specialized T cells to latch onto the target antigen and abolish the tumor cells.

According to the applicant, ciltacabtagene autoleucel is a CAR T-cell immunotherapy designed to recognize myeloma cells and target their destruction. Ciltacabtagene autoleucel's CAR T-cell technology consists of harvesting the patient's own T cells, programming them to express a chimeric antigen receptor that identifies BCMA, a protein highly expressed on the surface of malignant multiple myeloma B-lineage cells, and reinfusing these modified cells back into the patient where they bind to and eliminate myeloma tumor cells. The applicant asserts that, unlike the chimeric antigen receptor design of currently approved CAR T-cell immunotherapies, which are composed of a single-domain antibody (sdAbs), ciltacabtagene autoleucel is composed of two antibody binding domains that allow for high recognition of human BCMA (CD269) and elimination of BCMA expressing myeloma cells. The two distinct BCMA-binding domains, according to the applicant, confer avidity and distinguish ciltacabtagene autoleucel from other BCMA-targeting products. The BCMA binding domains are linked to the receptor's interior costimulatory (4–1BB) and signaling (CD3ζ) domains through a transmembrane linker (CD8a). These intracellular domains are critical components for T cell growth and anti-tumor activity [116] in the body once CAR T-cells are bound to a BCMA target on multiple myeloma cells.

With respect to the newness criterion, according to the applicant, ciltacabtagene autoleucel was granted Breakthrough Therapy designation in December 2019 for the treatment of patients with RRMM who have previously received a PI, an IMiD, and an anti-CD38 antibody. In December 2020, the applicant submitted a Biologic License Application (BLA) with the FDA but at the time of the development of this proposed rule, it has not yet received FDA approval. The applicant stated that procedures involving the administration of ciltacabtagene autoleucel can be reported using the following ICD–10–PCS procedure codes: XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3); and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). The applicant noted that there are currently no ICD–10–PCS codes that uniquely identify procedures involving the use of ciltacabtagene autoleucel. The applicant submitted a request for unique ICD–10–PCS codes to describe the administration of ciltacabtagene autoleucel beginning in FY 2022. The applicant also noted that they will submit a request for a Healthcare Common Procedure Coding System (HCPCS) code specific to the administration of ciltacabtagene autoleucel once the product is eligible for such a code.

As previously stated, if a technology meets all three of the substantial similarity criteria as previously described, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to whether a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, the applicant asserts that ciltacabtagene autoleucel has a unique mechanism of action because it has two distinct binding domains that confer avidity to the BCMA antigen, a 4–1BB costimulatory domain and a CD3z signaling domain, whereas other CAR T-cell products have only one target binding domain. However, we note that idecabtagnene vicleucel, another CAR T-cell therapy for which an application for new technology add-on payments was submitted for FY 2022, as discussed later in this section, appears to have a mechanism of action that is similar to that of ciltabatagene: A chimeric antigen receptor (CAR)-positive T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The idecabtagene vicleucel CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain, and a 4–1BB costimulatory domain. Antigen-specific activation of idecabtagene vicleucel results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells.

The applicant also asserts that its mechanism of action differs from Blenrep's mechanism of action. Blenrep is a BCMA-targeting agent indicated in the treatment of RRMM. According to the applicant, Blenrep belongs to the class of antibody-drug conjugates, which are therapies that are essentially composed of a monoclonal antibody linked to a toxic drug. Once the antibody portion of Blenrep recognizes BCMA on multiple myeloma cells, the toxin is released into cells, resulting in cell death. Therefore, according to the applicant, ciltacbtagene autoleucel's mechanism of action differs from Blenrep's. Additionally, the applicant states that there is currently no commercially available CAR T-cell product that binds to the BCMA antigen. Lastly, the applicant provided a list of other currently available treatments for multiple myeloma and a description of their mechanisms of action (Table 1).

[114] June CH, Sadelain M. Chimeric Antigen Receptor Therapy. N Engl J Med. 2018 Jul 5;379(1):64–73.

[115] Sadelain M. Chimeric antigen receptors: driving immunology towards synthetic biology. Curr Opin Immunol. 2016 Aug;41:68–76.

[116] Maher J, Brentjens RJ, Gunset G, Rivière I, Sadelain M. Human T-lymphocyte cytotoxicity and proliferation directed by a single chimeric TCRzeta/CD28 receptor.

TABLE 1: CURRENTLY AVAILABLE TREATMENT OPTIONS FOR MULTIPLE MYELOMA AND DESCRIBED MECHANISM OF ACTION

Treatment Class	Mechanism of Action
Proteasome Inhibitors (PI)[117]	• Interferes with the degradation of proteins within the cells • Myeloma cells are sensitive to this inhibition
Immunomodulatory drugs[117]	• Possess multiple antimyeloma properties including immune modulation, antiangiogenic, anti-inflammatory, and antiproliferative effects
Monoclonal antibodies (MABS)[117]	• Target specific proteins on myeloma cells, which may activate immune responses
Antibody-drug Conjugates[118]	• Antibody that specifically recognizes the BCMA protein — a protein found on the surface of myeloma cells
Histone Deacetylase Inhibitors (HDACIDS)	• Can cause apoptosis of myeloma cells through effects on gene regulation
Corticosteroids[119]	• Can cause apoptosis of myeloma cells
Conventional chemotherapy[120]	• An approach that targets dividing cells
Selective Inhibitor of Nuclear export (SINES)[121]	• Inhibits exportin-1 (XPO) resulting in activation of tumor suppressor proteins, glucocorticoid receptors, and immune response regulators thereby inducing cell cycle arrest and apoptosis

With regard to whether a product is assigned to the same DRG when compared to an existing technology, the applicant expects that cases involving the administration of ciltacabtagene autoleucel will be assigned to the same MS–DRG, MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), as other CAR T-cell therapies.

With regard to whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserts that ciltacabtagene autoleucel is indicated for a broader population than other available therapies, specifically multiple myeloma patients having received three prior therapies.

In summary, the applicant asserts that ciltacabtagene autoleucel meets the newness criterion and is not substantially similar to other available therapies because it has a unique mechanism of action with two distinct binding domains that confer avidity to the BCMA antigen, and because it treats a different patient population, RRMM patients who received three prior therapies. However, we note that ciltacabtagene autoleucel may have a similar mechanism of action to that of idecabtagene vicleucel, for which we received an application for new technology add-on payments for FY 2022 for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Per the new technology add-on payment application for idecabtagene vicleucel, the technology's mechanism of action is described as targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The chimeric antigen receptor (CAR) construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain, and a 4–1BB costimulatory domain. Antigen-specific activation of idecabtagene vicleucel results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells. Because of the potential similarity with the BCMA antigen and other actions, we believe that the mechanism of action for ciltacabtagene autoleucel may be the same or similar to that of idecabtagene vicleucel.

We believe that ciltacabtagene autoleucel may not treat the same or similar patient population as currently existing treatments. However, we believe that ciltacabtagene autoleucel and idecabtagene vicleucel may treat the same or similar disease (RRMM) in the same or similar patient population (patients who have previously received a proteasome inhibitor (PI), and immunomodulatory agent (IMiD) and an anti-CD38 antibody). Accordingly, as it appears that ciltacabtagene autoleucel and idecabtagene vicleucel are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action and would be assigned to the same MS–DRG, we believe that these technologies may be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments. We are interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether idecabtagene vicleucel and ciltacabtagne autoleucel are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comment on whether ciltacabtagene autoleucel meets the newness criterion, including whether ciltacabtagene autoleucel is substantially similar to idecabtagene vicleucel and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

[117] Cook G, et al. Crit Rev Oncol Hematol. 2018;121:74–89.

[118] Nejadmoghaddam MR, et al. Avicennna J Med Biotechnol. 2019;11(1):3–23.

[119] Pufall MA. Adv Exp Med Biol. 2015;872:315–33.

[120] Siddik ZH. The Cancer Handbook. New York: John Wiley & Sons, Ltd; 2002.

[121] Podar K, et al. Expert Opin Pharmacother. 2020 Mar;21(4):399–408.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR correction notice (December 1, 2020) file to identify potential cases representing patients who may be eligible for treatment using Ciltacabtagene autoleucel. In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The following ICD–10–CM diagnosis codes were used to identify claims involving multiple myeloma procedures.

Code	Code Descriptor
C90.0	Multiple myeloma
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse

The applicant chose to limit its analysis to MS–DRG 016 (Autologous Bone Marrow Transplant W CC/MCC or T-Cell Immunotherapy) because patients receiving autologous bone marrow transplant (BMT) are generally patients with relapsed or refractory multiple myeloma and are most similar to patients who would be eligible to receive CAR T-cell therapy. The claim search conducted by the applicant resulted in 1,215 claims mapped to MS–DRG 016 using the FY 2019 MedPAR. The applicant determined an average unstandardized case weighted charge per case of $1,237,393. The applicant used the New Technology Threshold for FY 2022 from the FY 2021 IPPS/LTCH PPS final rule for MS–DRG 018. The applicant removed all charges in the drug cost center for the prior technology because, according to the applicant, it is not possible to differentiate between different drugs on inpatient claims. The applicant added that this is likely an overestimate of the charges that would be replaced by the use of ciltacabtagene autoleucel. The applicant then standardized the charges using the FY 2019 final rule impact file. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used the inverse of a simulated alternative cost-to-charge ratio (CCR) specifically for CAR T cell therapies to account for CAR T-cell therapies' higher costs compared to other drugs and the potential for hospitals' charging practices to differ for these drugs. To determine this alternative CCR for CAR T-cell therapies, the applicant referred to the FY 2021 IPPS final rule AOR/BOR file and calculated an alternative markup percentage by dividing the AOR drug charges within MS–DRG 018 by the number of cases to determine a per case drug charge. The applicant then divided the drug charges per case by $373,000, the acquisition cost of YESCARTA and KYMRIAH, the CAR T-cell products used in those claims, to arrive at a CCR of 0.295. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,646,522, which it stated exceeded the average case-weighted threshold amount of $1,251,126. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR, we are uncertain how representative this data is for use in the applicant's cost analyses given this potential for variability.

We continue to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

We invite public comment on whether ciltacabtagene autoleucel meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that it believes that ciltacabtagene autoleucel represents a substantial clinical improvement over existing technologies because it: (1) Offers a treatment for a patient population with limited options and continued disease progression, despite having been treated with multiple prior therapies; and (2) provides a significantly improved clinical outcome relative to other therapies, either approved or still under FDA review, used in the relapsed and refractory multiple myeloma setting. With regard to the applicant's assertion that ciltacabtagene autoleucel offers a treatment for a patient population with limited options and continued disease progression, despite having been treated with multiple prior therapies, the applicant cited results from the CARTITUDE–1 STUDY, a Phase 1b/2, open-label, multicenter, multi-national (including US) study to evaluate the safety and efficacy of ciltacabtagene autoleucel in adult patients who have RRMM who have previously received a PI, an IMiD, and an anti-CD38 antibody. The applicant asserts that ciltacabtagene autoleucel was granted Breakthrough Therapy designation for patients who have RRMM who have previously received a PI, an IMiD, and an anti-CD38 antibody, based on data from the Phase1b/2 CARTITUDE–1 study. One hundred thirteen patients were enrolled in the study. Sixteen patients discontinued the study, including 9 patients who died due to progressive disease. Ninety-seven patients received ciltacabtagene autoleucel. The Phase 1b portion of the study included 29 of the 97 patients.

Two patients died during the study: one due to CRS and one due to acute myeloid leukemia (not treatment-related). Twenty-four of the remaining patients were ongoing in the Phase 1b dose confirmation period, with an additional 59 patients ongoing in the Phase 2 portion. The primary objective of the Phase 1b portion of the trial was to confirm the safety of the selected dose based on the data from the ongoing Phase 1 trial in China (Legend-2), as discussed later in this section. The primary objective of the Phase 2 portion of the trial is to evaluate the efficacy of ciltacabtagene autoleucel.

The applicant asserts that at median follow-up of 12.4 months, ciltacabtagene autoleucel led to a 97% overall response rate (ORR) in all 97 study patients who

received ciltacabtagene autoleucel.[122] The applicant asserts that this unprecedented overall response rate of (97%), represents early, deep, and durable responses in all patients, minimal residual disease negativity (meaning minimal residual cancer cells after treatment to the -nth degree) in the majority of patients who achieved a complete response (CR) and a very manageable toxicity profile. The applicant provided a comparison of the ORR in phase 1 studies for other therapies used to treat RRMM and noted the following: idecabtagene vicleucel ORR 73%,[123] daratumumab ORR 31%,[124] Selinexor ORR 26% [125] and Blenrep ORR 31%.[126]

The applicant further asserts that ciltacabtagene autoleucel led to early and deep clinical responses in the phase1b/2 portion of the CARTITUDE–1 study at median follow up of 12.4 months. Results of CARTITUDE–1 showed a 97% overall response rate (ORR) with 67% of patients attaining a stringent complete response (sCR) and 93% of patients attaining a very good partial response (VGPR) or better after receiving a low dose (median of 0.72 million CAR T-cells per kilogram) of ciltacabtagene autoleucel within approximately a year. ORR and depth of response were independent of BCMA expression on myeloma cells at baseline. The median time to first response was one month (range, 0.9–8.5).[127]

The applicant also asserted that most patients attained a status of minimal residual disease (MRD)-negativity by the time they were evaluable for a complete response (CR). Of evaluable patients, 93.0% achieved MRD 10^{-5} negativity. Fifty-eight percent of patients were both MRD negative and in sCR at MRD detection level of 10^{-5}. Median time to MRD 10^{-5} negativity: 1 month (0.8–7.7). Among patients with 6 months individual follow-up, most had ciltacabtagene autoleucel CAR+ T-cells below the level of quantification (2 cells/μL) in peripheral blood.

In addition, progression-free survival (PFS) at 12 months was 77% (95% CI; 66.0–84.37).[128] The applicant believes this represents a substantial clinical improvement when compared to existing technologies that treat RRMM. The applicant further asserts that nearly all of the individuals participating in the study (22 of the 29 patients) were alive and continued showing no signs of disease progression after a period of 9 months. Median PFS was not reached. At median follow-up of 12.4 months, there were 14 deaths during the Phase 1b/2 study: One due to cytokine release syndrome (CRS) and hemophagocytic lymphohistiocytosis (HLH), one due to neurotoxicity, and 12 due to other causes.[98] The applicant asserts that the CRS was manageable in most patients. CRS was the most common adverse event (AE) (94.8%) observed in the CARTITUDE–1 study. The median time to onset of CRS was 7 days (range 1–12 days) post ciltacabtagene autoleucel infusion. The median duration of CRS was 4 days. Eighty-seven patients (94.6%) experienced Grade 1–2 CRS and 5 patients (5% experienced grade 3 or greater CRS)122.

The applicant noted that neurotoxicity with immune effector cell-associated neurotoxicity syndrome (ICANS) was infrequently observed in the context of CRS and was generally low grade. Neurotoxicity with ICANS was observed in 20 patients (20.6%) including 10 patients (10.3%) with Grade 3 or above toxicity.122

The LEGEND–2 study [129] is an ongoing Phase 1, single-arm, open-label, multicenter, first-in-human trial to determine the safety and efficacy of ciltacabtagene autoleucel (LCAR–B38M in China) in the treatment of patients with relapsed or refractory multiple myeloma. Enrollment in this investigator-initiated study (study proposed, initiated, and conducted by an investigator that is funded by industry) completed in November 2017; a total of 74 patients with RRMM have been treated with ciltacabtagene autoleucel CAR T-cell therapy. The clinical cutoff for the analysis of these 74 patients was February 6, 2018 with updated survival and efficacy data as of November 26, 2019 (which represents 2 years of follow-up from the date of the last subject's infusion). Seventeen patients (17/57–29%) died during the study and follow up period (19 months) mostly due to progressive disease. None were related to cytokine release syndrome or neurotoxicity, the two most common adverse events associated with CAR T-cell therapy. At data cutoff, 57 patients had received LCAR–B38M CAR T-cells.

The applicant further asserts that outcomes from the LEGEND–2 study show that cilltacabtagene autoleucel provides a significantly improved clinical outcome relative to other therapies, either approved or still under FDA review, used in the RRMM setting. At cutoff, the median follow-up was 19 months [17–22]. The overall survival (OS) rate at 18 months was 68% with a median duration of response (mDOR) of 22 months. Of MRD-negative patients with CR, 91% were still alive at data cut, with a 27 month mDOR. The median time to first response was 1.1 months. There was no relationship between best response and baseline BCMA expression level or weight-adjusted CAR T-cells infused.[105]

The applicant asserts that of patients in the LEGEND–2 study with CR, 39 of 42 were minimal residual disease negative (MRD-neg) and remained RRMM progression-free. The median PFS rate for all treated patients was 20 months; median PFS for MRD-neg patients with CR was 28 months. At 18 months, the PFS rate was 50% for all patients and 71% for MRD-neg patients with CR. Seventeen patients died during the study and the follow-up period. The causes of death included progressive disease (PD; n=11), disease relapse, PD with lung infection, suicide after PD, esophageal carcinoma, infection, pulmonary embolism and acute coronary syndrome (n=1 each). Of these, 4 did not achieve partial response (PR) or better; and 1 was not evaluable.

From the LEGEND–2 study, the median time to onset of CRS was 9 days (range, 1–19) with a median duration of 9 days (range, 3–57); all but 1 CRS events resolved. Tocilizumab (46%), oxygen (35%), vasopressor (11%), and intubation (1 patient) were used to treat CRS. Neurotoxicity with grade 1 aphasia, agitation and seizure-like activity was observed in 1 patient in the LEGEND–2 study. The applicant believes that since ciltacabtagene autoleucel displayed a manageable CRS safety profile that it represents a substantial clinical improvement over existing therapies.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ciltacabtagene autoleucel, we note that there are no head-to-head comparisons of ciltacabtagene autoleucel and other CAR T-cell therapies and BCMA-targeted

[122] Madduri D et. al. CARTITUDE–1: Phase 1b/2 Study of Ciltacabtagene Autoleucel, a B-Cell Maturation Antigen–Directed Chimeric Antigen Receptor T-Cell Therapy, in Relapsed/Refractory Multiple Myeloma

[123] Munshi et al. ASCO 2020

[124] Usmari et al. Blood 2016, 128(1), 37–44.

[125] Chari A et al N Engl J Med 22019, 38 2(8);727–738

[126] DREAMM2 Lonai S et al Lancet 2019.

[127] Berdeja JG, Madduri D, Usmani SZ, Singh I, Zudaire E, Yeh TM, Allred AJ, Olyslager Y, Banerjee A, Goldberg JD, Schecter S, Geng D, Wu X, Carrasco-Alfonso M, Rizvi S, Fan F, Jakubowiak AJ, Jagannath S. Update of CARTITUDE–1: A phase Ib/II study of JNJ–4528, a B-cell maturation antigen (BCMA)-directed CAR–T cell therapy, in relapsed/refractory multiple myeloma. Journal of Clinical Oncology. 2020 38:15_suppl, 8505–8505.

[128] Ibid.

[129] Zhao et al. Journal of Hematology and Oncology. (2018) 11:141.

therapies. We also note that the applicant chose to use ORR data as a measure of substantial clinical improvement rather than the available, and more clinically relevant, OS data.

We are inviting public comment on whether ciltacabtagene autolecuel meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ciltacabtagene autoleucel.

e. COSELA (trilaciclib)

G1 Therapeutics submitted an application for new technology add-on payments for Trilaciclib for FY 2022. COSELA (trilaciclib) is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES–SCLC).[130]

According to the applicant, Trilaciclib is a first-in-class myelopreservation therapy that has the potential to mitigate chemotherapy-induced myelosuppression (CIM). Trilaciclib is a selective, transient inhibitor of cyclin dependent kinases 4 and 6 (CDK4/6) with potential antineoplastic and chemoprotective activities. CDK4 and CDK6 are key regulators of the G1 cell-cycle checkpoint and play important roles in cell proliferation and associated biological processes. One of the most common pathways dysregulated in cancer is the cyclin D–cyclin-dependent kinase four or six (CDK4/6)–retinoblastoma (RB) pathway. Trilaciclib arrests hematopoietic stem and progenitor (HSPCs) bone marrow cells in the G1 phase of the cell cycle during chemotherapy exposure, protecting them from chemotherapy-induced damage.

According to the applicant, the defining characteristic of cancer is uncontrolled cellular proliferation, a phenomenon that requires tumor cells to avoid or disable normal, physiologic cell-cycle regulation. While there are both CDK 4/6 independent and dependent cells, HSPCs and immune cells are CDK 4/6 dependent whereas SCLC cells are CDK 4/6 independent. According to the applicant, the transient arrest of HSPCs and lymphocytes by trilaciclib during the administration of chemotherapy is thought to have a number of beneficial effects, including a reduction in chemotherapy-induced myelosuppression and preservation of immune function, as well as an enhanced immune response.[131] [132] [133] Specifically, SCLC cells replicate independently of CDK 4/6 and therefore these cells are damaged by chemotherapy. Because HSPCs and lymphocytes are CDK 4/6 dependent, trilaciclib's mechanism of action is believed to preserve these cells by temporarily arresting their proliferation during chemotherapy. In this way, trilaciclib reduces chemotherapy-induced myelosuppression in patients with extensive-stage small-cell lung cancer (ES–SCLC).[134] The applicant also asserted that in preclinical models, CDK4/6 inhibition by trilaciclib also alters the tumor immune microenvironment through transient inhibition of the immune cells known as lymphocytes that are also dependent on CDK4/6 activity for proliferation.[135]

According to the applicant, chemotherapy remains the cornerstone of treatment for extensive stage small cell lung cancer (ES–SCLC). The applicant asserted that almost all of the ~18,600 ES–SCLC patients diagnosed each year are treated with platinum/etoposide-containing or topotecan-containing chemotherapy regimens. Chemotherapy drugs target cells at different phases of the cell cycle. According to the applicant, systemic chemotherapy, alone or in combination with immune checkpoint inhibitors, is the standard of care for patients with advanced SCLC. Additionally, per the applicant, rescue interventions, including growth factors and blood transfusions, are commonly routine therapies for SCLC. The applicant also indicated that granulocyte colony-stimulating factors (G–CSFs) only address neutropenia, while erythropoiesis stimulating agent (ESAs) and red blood cell (RBC) transfusions only address anemia, and there is no available treatment that broadly mitigates myelosuppressive effects and their corresponding impact on patient well-being before chemotherapy damage occurs.

COSELA (trilaciclib) received FDA's New Drug Application approval on February 12, 2021. COSELA is for intravenous use only. The recommended dose of COSELA is 240 mg/m2 as a 30-minute intravenous infusion completed within four hours prior to the start of chemotherapy on each day chemotherapy is administered.[136] The applicant also stated that in 2019, trilaciclib was granted Breakthrough Therapy Designation for the mitigation of clinically significant chemotherapy-induced myelosuppression in adult patients with SCLC. The applicant submitted a request for a new ICD–10–PCS code as the applicant states that there are no existing ICD–10–PCS codes that uniquely identify the administration of trilaciclib.

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that trilaciclib, also referred to as G1T28, has a unique mechanism of action as a small molecule, competitive inhibitor of CDK4/6, with potential antineoplastic and chemoprotective activities. The applicant stated that upon administration, trilaciclib binds to and inhibits the activity of CDK4/6, thereby blocking the phosphorylation of

[130] G1 Therapeutics Inc., Rev. 2/2021, COSELA prescribing information: *https://www.g1therapeutics.com/cosela/pi/#:~:text=COSELA%20is%20indicated%20to%20decrease,cancer%20(ES%2DSCLC).&text=The%20recommended%20dose%20of%20COSELA%20is%20240%20mg%2Fm2%20per%20dose.*

[131] Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib (T) decreases myelosuppression in extensive-stage small cell lung cancer (ES–SCLC) patients receiving first-line chemotherapy plus atezolizumab. Ann Oncol. 2019;30:v713, Abstract 1742PD: *https://www.g1741therapeutics.com/file.cfm/1734/docs/tr-G1741_ESMO2019_Daniel.pdf.*

[132] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: a phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[133] Hart LL, Andric ZG, Hussein MA, et al. Effect of trilaciclib, a CDK 4/6 inhibitor, on myelosuppression in patients with previously treated extensive-stage small cell lung cancer receiving topotecan. J Clin Oncol. 2019;37(15_suppl): Abstract 8505: *https://www.g8501therapeutics.com/file.cfm/8534/docs/tr-G8501T8528–8503%8520ASCO%202019%202020Oral%202020Presentation%20060119–20060111.pdf.*

[134] Donjerkovic D, Scott DW. Regulation of the G1 phase of the mammalian cell cycle. *Cell Res.* 2000;10(1):1–16.

[135] Lai AY, Sorrentino JA, Dragnev KH, et al. CDK4/6 inhibition enhances antitumor efficacy of chemotherapy and immune checkpoint inhibitor combinations in preclinical models and enhances T-cell activation in patients with SCLC receiving chemotherapy. J Immunother Cancer. 2020;0:e000847. doi:10.1136/jitc-2020–000847.

[136] G1 Therapeutics Inc., Rev. 2/2021, COSELA prescribing information: *https://www.g1therapeutics.com/cosela/pi/#:~:text=COSELA%20is%20indicated%20to%20decrease,cancer%20(ES%2DSCLC).&text=The%20recommended%20dose%20of%20COSELA%20is%20240%20mg%2Fm2%20per%20dose.*

the retinoblastoma protein (Rb) in early G1. This prevents G1/S phase transition, causing cell cycle arrest in the G1 phase and induced apoptosis, which inhibits the proliferation of CDK4/6-overexpressing tumor cells. In patients with CDK4/6-independent tumor cells, G1T28 may protect against multi-lineage chemotherapy-induced myelosuppression (CIM) by transiently and reversibly inducing G1 cell cycle arrest in hematopoietic stem and progenitor cells (HSPCs) and preventing transition to the S phase. Per the applicant, this protects all hematopoietic lineages, including red blood cells, platelets, neutrophils and lymphocytes, from the DNA-damaging effects of certain chemotherapeutics and preserves the function of the bone marrow and the immune system.

The applicant stated that the cell cycle consists of four distinct phases, Gap 1 phase (G_1), S phase, Gap 2 (G_2) post-synthesis phase, and the M phase.[137] Regulation of this process is maintained by a series of highly conserved proteins referred to as cyclins, and their catalytic binding partners, CDKs. The CDKs are a family of enzymes that control several cellular processes in mammalian cells, including the modulation of the cell cycle via binding to cyclins A–E, which results in the activation of transcription factors that regulate the cellular transition from G1 (growth phase) to S (DNA replication) and G2 (growth phase) to M (mitosis).[138]

According to the applicant, the G1-to-S checkpoint is a critical restriction point in the process of cell division. Cells are maintained in a quiescent state until the proper signal is achieved for reentry into the cell cycle. Throughout G1, expression of the D-type cyclins (D1, D2, D3) increases until active complexes with CDK4/6 are formed. Active CDK4/6 complexes partially phosphorylate RB, which allows partial depression of the transcription factor E2F. This induces additional transcript production of cyclin E1, which binds CDK2 to form active complexes that result in the hyperphosphorylation of RB and drives the cells through late G1 into S phase. Inhibition of cyclin D–CDK4/6 by the tumor suppressor CDKN2A leads to a G1 arrest and cell-cycle progression is halted.[139]

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that trilaciclib will be assigned the same MS–DRG as existing technologies. The applicant did not explicitly state to which MS–DRG(s) trilaciclib would be assigned, but included MS–DRGs 180 (Respiratory Neoplasms with MCC), 181 (Respiratory Neoplasms with CC), and 182 (Respiratory Neoplasms without CC/MCC) in its cost analysis.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that trilaciclib is the only proactive (preventive) multilineage (erythrocytes, leukocytes, and thrombocytes, neutrophils and lymphocytes) therapy given as a 30-minute infusion administered prior to chemotherapy on each day of chemotherapy. Due to its mechanism of action, trilaciclib's benefit is coupled to its administration schedule (that is, trilaciclib must be administered prior to chemotherapy to ensure G1 arrest of HSPCs when those cells are exposed to cytotoxic chemotherapy). According to the applicant, this therapeutic paradigm contrasts with standard available treatment options and interventions that are administered after chemotherapy to reactively reduce or treat chemotherapy side effects. The applicant asserted that typical supportive care rescue interventions such as growth factors (G–CSFs, ESAs) and red blood cell (RBC) transfusions are used after chemotherapy causes damage to stem cells. Current supportive care therapies are used reactively to treat single cell lineage specific (leukocytes and erythrocytes) complications,[140] such as neutropenia and anemia. Additionally, the applicant indicated that growth factor and RBC transfusion use are known to carry a number of risks and cause complications and adverse events.

We note that the information provided by the applicant in response to whether trilaciclib treats the same or similar type of disease or the same or similar patient population, appears to only speak to the first criterion and whether trilaciclib has a mechanism of action that is different than existing technologies; however, we believe trilaciclib appears to treat the same patient population and disease as existing therapies. We are inviting public comments on whether trilaciclib is substantially similar to an existing technology and whether it meets the newness criterion.

With respect to the cost criterion, the applicant conducted the following analysis to demonstrate that trilaciclib meets the cost criterion. In identifying the cost of trilaciclib, the applicant stated that dosing is based on body surface area, 240 mg/m^2 with an average of two vials (300mg each) per patient per dose. To identify cases that may be eligible for the use of trilaciclib, the applicant searched the FY 2019 MedPAR LDS file for claims reporting an ICD–10–PCS code of category C34 through C34.92 (Malignant neoplasm related to the bronchus, lobe, or lung) as noted in the following table.

[137] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. Poster presented at: IASLC: 2020 North America Conference on Lung Cancer; October 16–17, 2020; Virtual congress.

[138] Asghar U, Witkiewicz AK, Turner NC, Knudsen ES. The history and future of targeting cyclin-dependent kinases in cancer therapy. Nat Rev Drug Discov. 2015;14(2):130–146.

[139] Donjerkovic D, Scott DW. Regulation of the G1 phase of the mammalian cell cycle. Cell Res. 2000;10(1):1–16.

[140] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors. Version 1.2020. 27 January. 2020.

Code	Code Descriptor
C34	Malignant neoplasm of bronchus and lung
C34.0	Malignant neoplasm of main bronchus
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	Malignant neoplasm of upper lobe, bronchus or lung

Code	Code Descriptor
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.9	Malignant neoplasm of unspecified part of bronchus or lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

According to the applicant, based on the advice of clinical experts, it limited case selection criteria to claims that included one of MS–DRGs 180, 181, or 182. The applicant then randomly selected 15% of the claims from the sample to account for the fact that SCLC comprises 15% of lung cancer cases.[141] Based on the FY 2019 MedPAR LDS file, the applicant identified 3,500 cases. The applicant noted that 2,346 cases mapped to MS–DRG 180; 1,085 cases

[141] Govindan R, et al. *J Clin Oncol.* 2006;24:4539–44. Byers LA, Rudin CM. *Cancer.* 2015;121:664–72.

mapped to MS–DRG 181; and 69 cases mapped to MS–DRG 182.

Using these 3,500 cases, the applicant then calculated the unstandardized average charges per case for each MS–DRG. Because the use of trilaciclib results in approximately half of patients no longer needing drugs used to counter the effects of chemotherapy during the inpatient stay, the applicant removed 50% of the drug charges for the technology being replaced.

The applicant then standardized the charges using the 2019 IPPS/LTCH PPS final rule impact file and inflated the charges by 1.13218 or 13.2 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule. The applicant then added the charges for trilaciclib by converting the costs to a charge by dividing the cost by the national average cost-to-charge ratio of 0.187 for pharmacy from the FY 2021 IPPS/LTCH PPS final rule.

Using the data file thresholds associated with the FY 2021 IPPS/LTCH PPS final rule correction notice, the average case-weighted threshold amount was $57,031. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $95,701. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

With respect to the cost criterion, we note that in listing the codes it used to identify cases that may be eligible for the use of trilaciclib, the applicant provided several ICD–10 codes that lack four digits and thus, are considered invalid. We would be interested in understanding the basis for the applicant's choice of codes. We also note that in its analysis, the applicant randomly selected 15% of the claims from the sample to account for the fact that SCLC comprises 15% of lung cancer cases. In so doing, the applicant is making the assumption that SCLC cases are randomly distributed amongst all cases from which the applicant sampled. By randomly sampling the population, the applicant is selecting a subsample that is ideally similar to the population with less variance. It may be the case that SCLC cases are systematically different from other cases in the population. If this is true, then a random sample may not be appropriate. Accordingly, we question the appropriateness of the sampling used and whether it accurately represents cases that would use the technology.

Finally, with respect to pricing, it appears that the applicant's final inflated average case-weighted standardized charge per case reflects pricing prior to the availability of more current total wholesale acquisition cost. We therefore request that the applicant update its cost analysis to reflect the final inflated average case weighted standardized charge per case based on this more current information. We are inviting public comment on whether trilaciclib meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that trilaciclib represents a substantial clinical improvement over existing technologies because it offers a treatment option for patients unresponsive to or ineligible for currently available treatments and improves clinical outcomes for a patient population as compared to currently available treatments. The applicant stated that chemotherapy-induced myelosuppression (CIM) is typically managed with treatment dose delays and reductions due to the slow recovery of bone marrow after a course of chemotherapy.[142] The applicant also stated that CIM is managed with rescue interventions including hematopoietic growth factors (G–CSFs and ESAs) and by RBC and platelet transfusions.[143] [144] Per the applicant, despite the availability and use of these treatment options, CIM continues to be of clinical significance and remains a central concern in the delivery of chemotherapy.[145] [146] The applicant further stated that myelosuppression results in dose reductions, dose delays, and/or dose discontinuations, affecting the dose intensity and intended antitumor efficacy of chemotherapy.[147] Per the applicant, the supportive care interventions for treatment of myelosuppression are suboptimal and are often administered reactively, do not protect the bone marrow from chemotherapy-induced cytotoxic effects, are specific to single hematopoietic lineages, and impart their own risks for adverse reactions.[148] The applicant concluded by stating that new approaches that proactively prevent chemotherapy-induced damage and its associated consequences, whilst not decreasing the efficacy of chemotherapy, are urgently needed to improve care of patients with ES–SCLC.[149]

In regard to the claim that the use of trilaciclib significantly improves clinical outcomes for a patient population as compared to currently available treatments, the applicant stated that the administration of trilaciclib prior to chemotherapy in patients with SCLC prevented chemotherapy-induced neutropenia, reduced chemotherapy-induced anemia, reduced CIM or sepsis-related hospitalizations, and has the potential to improve the management and quality of life of patients receiving myelosuppressive chemotherapy as compared to placebo.[150]

The applicant presented eight claims in support of the assertion that trilaciclib represents substantial clinical improvement over existing technologies in the mitigation of clinically significant chemotherapy-induced myelosupression in adult patients with SCLC.

In its first and second claims, the applicant asserted that trilaciclib reduces the mean duration of severe G4 neutropenia in cycle 1 of chemotherapy and reduces the proportion of patients experiencing severe G4 neutropenia in comparison to placebo. The applicant submitted three sources in support of these claims. First, the applicant submitted a poster presentation from Daniel, et. al., describing a global, randomized, double-blind, placebo-controlled, multicenter, phase 2 study that assessed the potential of trilaciclib to reduce the incidence and consequences of chemotherapy-induced myelosuppression in patients with newly diagnosed ES–SCLC treated with etoposide, carboplatin, and atezolizumab. One hundred seven eligible patients were randomized to

[142] Crawford J, Dale DC, Lyman GH. Chemotherapy-induced neutropenia: Risks, consequences, and new directions for its management. Cancer. 2004;100(2):228.

[143] Kurtin S. Myeloid Toxicity of Cancer Treatment. *J Adv Pract Oncol* 2012;3:209–24.

[144] Asghar U, Witkiewicz AK, Turner NC, Knudsen ES. The history and future of targeting cyclin-dependent kinases in cancer therapy. Nat Rev Drug Discov. 2015;14(2):130–46.

[145] Crawford J, Dale DC, Lyman GH. Chemotherapy-induced neutropenia: Risks, consequences, and new directions for its management. Cancer. 2004;100(2):228.

[146] Lyman GH. Chemotherapy dose intensity and quality cancer care. Oncology (Williston Park). 2006;20(14 Suppl 9):16–25.

[147] Smith RE. Trends in recommendations for myelosuppressive chemotherapy for the treatment of solid tumors. J Natl Compr Canc Netw. 2006;4(7):649–58.

[148] Bisi JE, Sorrentino JA, Roberts PJ, Tavares FX, Strum JC. Preclinical characterization of G1T28: a novel CDK4/6 inhibitor for reduction of chemotherapy-induced myelosuppression. Mol Cancer Ther. 2016;15(5):783–93.

[149] Nurgali K, Jagoe T, Raquel Abalo R. Editorial: Adverse Effects of Cancer Chemotherapy: Anything New to Improve Tolerance and Reduce Sequelae? Front Pharmacol. 2018;9:245.

[150] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. Poster presented at: IASLC: 2020 North America Conference on Lung Cancer; October 16–17, 2020; Virtual congress.

receive trilaciclib (n = 53) or placebo (n = 54). The primary endpoints were mean duration of severe neutropenia (SN) in cycle 1 and percent of patients with grade 4 SN. Results summarized mean duration of SN in cycle 1 as 0 days with trilaciclib and 4 days with placebo, and percent of patients with grade 4 SN as 1.9% vs 49.1%, respectively.[151]

Second, the applicant submitted an article by Weiss, et. al., summarizing a phase II randomized, double-blind placebo-controlled study of the safety, efficacy and pharmacokinetics (PK) of trilaciclib in combination with etoposide/carboplatin (E/P) therapy for treatment-naive extensive-stage small-cell lung cancer patients. Thirty-nine patients were included in the trilaciclib group versus 38 in the placebo group. The applicant stated that treatment with trilaciclib resulted in a reduced mean duration of severe G4 neutropenia in cycle 1 (0 days versus 3 days in placebo) and reduced proportion of patients experiencing severe G4 neutropenia for trilaciclib (5% versus 43%).[152]

Third, the applicant submitted a presentation from Hart, et. al., describing a randomized, double-blind, placebo-controlled, phase 2 study to compare the results of 32 patients receiving Trilaciclib versus 28 receiving placebo in patients being treated with topotecan for previously treated ES–SCLC. Primary endpoints were mean duration of SN in cycle 1 and the percentage of patients with SN. Results demonstrated that the mean duration of severe G4 neutropenia in cycle 1 was reported at 2 days for trilaciclib versus eight days for placebo. The proportion of patients experiencing severe G4 neutropenia was reported at 41% for trilaciclib versus 76% for placebo.[153]

In the third claim, the applicant asserted that trilaciclib reduces the proportion of patients experiencing febrile neutropenia treatment emergent adverse events (TEAE) in comparison to placebo. In the fourth claim, the applicant asserted that trilaciclib decreases the rate of therapeutic intervention with G–CSF in comparison to placebo, noting that growth factors are known to carry a number of risks, cause complications and adverse events. In the fifth claim, the applicant asserted that trilaciclib reduces the proportion of patients experiencing grade 3/4 anemia in comparison to placebo. In the sixth claim, the applicant asserted that trilaciclib decreases the rate of therapeutic intervention with red blood cell transfusions in comparison to placebo. To support these claims, the applicant submitted a 2020 poster presentation from Weiss, et. al., describing a pooled analysis across three RCTs that compared the proportion of ES–SCLC patients experiencing febrile neutropenia between trilaciclib and placebo. The trilaciclib group included 122 patients and the placebo group included 118 patients. The presentation reflected the following results: The proportion of patients experiencing febrile neutropenia for trilaciclib was 3% versus placebo at 9%; the rate of therapeutic intervention with G–CSF for trilaciclib at 29% versus 56% for placebo; the proportion of patients experiencing grade 3/4 anemia for trilaciclib at 20% versus 32% for placebo; and the rate of therapeutic intervention with red blood cell transfusions for trilaciclib at 15% versus 26% for placebo.[154]

In the seventh claim, the applicant asserted that trilaciclib delays time to deterioration in symptoms and functioning domains of patient-reported quality of life measures on Functional Assessment of Cancer Therapy (FACT) scores. The applicant submitted a 2019 presentation from Weiss, et. al., describing a pooled analysis across three RCTs. The applicant stated that trilaciclib delays time to confirmed deterioration in a variety of symptoms and functioning domains compared to placebo, for example: median of 4.7 months delay to deterioration for fatigue; median of 3.5 months delay for anemia; and median of 4 months delay for functional well-being.[155]

In the eighth claim, the applicant asserted that trilaciclib decreases the number of hospitalizations due to myelosuppression or sepsis. The applicant submitted a conference agenda referring to an oral presentation by Ferrarotto, et. al., at the North America Conference on Lung Cancer, October 16, 2020. The applicant stated that hospitalizations due to myelosuppression or sepsis occurred in significantly fewer patients and significantly less often among patients receiving trilaciclib prior to chemotherapy versus placebo though we were unable to locate support for this claim in the conference agenda submitted with the application.[156]

With respect to the substantial clinical improvement criterion, we note that the data submitted by the applicant included one published peer reviewed article from Weiss, et. al.,[157] abstracts from Daniel, et. al.,[158] and Hart, et. al.,[159] and references to trials exploring broader cohorts of small cell lung cancer, breast cancer and colon cancer patients. In addition, as summarized previously, we note that most of the studies submitted by the applicant had sample sizes fewer than 100 participants which may limit generalizability of the studies. With respect to the Weiss, et. al., study, we note that trilaciclib was compared with placebo at a significance level of two-sided $\alpha = 0.2$ which is much lower than the typical cutoff of 0.05 and may have increased the risk of false positives and interfered with the ability to draw conclusions that are based on statistical methods. We also note the lack of any statistical correction for multiple comparisons. We note that

[151] Daniel D, Kuchava V, Bondarenko I et al. Trilaciclib Decreases Myelosuppression in Extensive-Stage Small Cell Lung Cancer (ES–SCLC) Patients Receiving First-Line Chemotherapy Plus Atezolizumab [Poster Presentation]. European Society of Medical Oncology (ESMO). October, 2019; Barcelona, Spain.

[152] Weiss JM, Csoszi T, Maglakelidze M et al. Myelopreservation with the CDK4/6 inhibitor Trilaciclib in Patients with Small-Cell Lung Cancer Receiving First-Line Chemotherapy: A Phase Ib/Randomized Phase II Trial. Ann Oncol. 2019 ;30(10):1613–1621.

[153] Hart LL, Andric ZG, Hussein MA et al. Effect of Trilaciclib, a CDK4/6 Inhibitor, on Myelosuppression in Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer [Oral Presentation]. Presented at: American Society of Clinical Oncology (ASCO). June 2019; Chicago, US.

[154] Weiss J, Goldschmidt J, Andric Z et al. Myelopreservation and Reduced Use of Supportive Care with Trilaciclib in Patients with Small Cell Lung Cancer [Poster Presentation]. Presented at: American Society of Clinical Oncology (ASCO). May 2020.

[155] Weiss J, Skaltsa K, Gwaltney C, et al: Results from three phase 2 randomized, double-blind, placebo-controlled small cell lung cancer trials. 2019 Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology International Symposium on Supportive Care in Cancer. Abstract eP723. Presented June 21, 2019.

[156] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. [Oral Presentation]. Presented at: North America Conference on Lung Cancer, October 2020. *https://naclc2020.iaslc.org/program-at-a-glance/.*

[157] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: A phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[158] Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib (T) decreases myelosuppression in extensive-stage small cell lung cancer (ES–SCLC) patients receiving first-line chemotherapy plus atezolizumab. Ann Oncol. 2019;30:v713, Abstract 1742PD. *https://www.g1741therapeutics.com/file.cfm/1734/docs/tr-G1741_ESMO2019_Daniel.pdf.*

[159] Hart LL, Andric ZG, Hussein MA, et al. Effect of trilaciclib, a CDK ⅘ inhibitor, on myelosuppression in patients with previously treated extensive-stage small cell lung cancer receiving topotecan. J Clin Oncol. 2019;37(15_suppl): Abstract 8505: *https://www.g8501therapeutics.com/file.cfm/8534/docs/tr-G8501T8528–8503%8520ASCO%202019%202020Oral%202020Presentation%20060119–20060111.pdf.*

in sources provided by the applicant, mean duration of severe neutropenia was assessed in day increments.[160] [161] [162] [163] However, it is not clear that zero days would indicate that those patients experienced no severe neutropenia. Specifically, we question whether mean hours in severe neutropenia was evaluated or whether, in addition to the groupings by days, one day or less would be an appropriate value for inclusion. Finally, while the applicant referred to decreases in the number of hospitalizations, we note that the source provided was limited to a conference agenda that only linked to an abstract pertaining to reductions in utilization of supportive care interventions but did not reflect hospitalization rates.[164]

We invite public comments as to whether trilaciclib meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for trilaciclib.

f. Ellipsys® Vascular Access System

Avenu Medical, Inc. submitted an application for new technology add-on payments for the Ellipsys® Vascular Access System (''Ellipsys'') for FY 2022. Ellipsys is a device that enables percutaneous creation of an arteriovenous fistula (AVF), which is used to access the bloodstream for hemodialysis for the treatment of end-stage renal disease (ESRD). According to the applicant, to create the fistula, a physician inserts a crossing needle through the perforating vein and into the proximal radial artery in the forearm. A specialized catheter is then used to bring the artery and vein together. The two vessels are ''welded'' together with thermal resistance energy, creating an anastomosis. According to the applicant, the only means of creating an AVF was through open surgery before the approval of Ellipsys, and percutaneous AVF (pAVF) offers a number of advantages over surgical AVF (sAVF).

With respect to the newness criterion, the applicant for Ellipsys received 510(k) clearance from the FDA on August 9, 2019, with an indication for the creation of a proximal radial artery to perforating vein anastomosis via a retrograde venous access approach in patients with a minimum vessel diameter of 2.0mm and less than 1.5mm of separation between the artery and vein at the fistula creation site who have chronic kidney disease requiring dialysis.[165] The subject of this 510(k) clearance was an update to the Instructions for Use (IFU) to allow an additional procedural step for balloon dilation of the anastomosis junction at the radial artery and adjacent outflow vein of the AVF immediately after creation with the Ellipsys catheter. Per the applicant, the device was immediately available on the market. The applicant further stated that the device was originally approved under a De Novo clearance on June 22, 2018. Ellipsys also received two additional 510(k) clearances dated January 25, 2019 (minor change in the packaging of components) and October 5, 2018 (minor technological differences in the power control unit and minor enhancements to the catheter design) but the applicant states they are not regarded as material for this application. The FDA has classified Ellipsys as a Class II device under the generic name percutaneous catheter for creation of an arteriovenous fistula for hemodialysis access. The applicant stated that currently, two ICD–10–PCS codes identify procedures using Ellipsys: 031B3ZF (Bypass right radial artery to lower arm vein, percutaneous approach); and 031C3ZF (Bypass left radial artery to lower arm vein, percutaneous approach). However, since these codes also identify the WavelinQ™ EndoAVF System (''WavelinQ''), another percutaneous fistula device, Avenu Medical submitted a code request for a unique ICD–10–PCS code to distinctly identify Ellipsys beginning in FY 2022. The applicant stated this technology was first assigned HCPCS code C9754 on January 1, 2019, which was then replaced by HCPCS code G2170 on July 1, 2020. Per the applicant, WavelinQ was assigned HCPCS codes (C9755 replaced by G2171) with the same timing, and the codes for the 2 pAVF technologies are differentiated by the use of thermal resistance energy for Ellipsys and the use of radiofrequency energy for WavelinQ.

The applicant stated that hemodialysis access for the treatment of ESRD can be provided by catheter, graft, or AVF, of which AVF is generally preferred for patients whose vascular anatomy and condition permit it. Per the applicant, the only method for creating an AVF was through an open surgical approach until the introduction of Ellipsys and WavelinQ, two devices that use a percutaneous approach.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that Ellipsys uses a new mechanism of action compared to its initial clearance. Per the applicant, the current device included an additional step in the IFU, creating a different procedure profile and a different mechanism of action. The applicant states that the addition of this step, a balloon angioplasty performed within the same operative session as the creation of the pAVF, instead of days or weeks later, typically contributes to decreased time to maturation, improved initial flow, and helps avoid early thrombosis of the newly-created access, in addition to decreasing the number of secondary procedures required for maturation and maintenance. According to the applicant, the explicit inclusion of the step in the IFU, where it was not previously explicitly included, represents a new mechanism of action.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant generally stated that Ellipsys is assigned to the same MS–DRGs as existing technologies. According to information provided by the applicant,

[160] Weiss JM, Csoszi T, Maglakelidze M, et al. Myelopreservation with the CDK4/6 inhibitor trilaciclib in patients with small-cell lung cancer receiving first-line chemotherapy: A phase Ib/randomized phase II trial. Ann Oncol. 2019;30(10):1613–1621.

[161] Daniel D, Kuchava V, Bondarenko I, et al. Trilaciclib (T) decreases myelosuppression in extensive-stage small cell lung cancer (ES–SCLC) patients receiving first-line chemotherapy plus atezolizumab. Ann Oncol. 2019;30:v713, Abstract 1742PD: *https://www.g1741therapeutics.com/file.cfm/1734/docs/tr-G1741_ESMO2019_Daniel.pdf.*

[162] Hart LL, Andric ZG, Hussein MA et al. Effect of Trilaciclib, a CDK4/6 Inhibitor, on Myelosuppression in Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer [Oral Presentation]. Presented at: American Society of Clinical Oncology (ASCO). June 2019; Chicago, US.

[163] Weiss J, Goldschmidt J, Andric Z et al. Myelopreservation and Reduced Use of Supportive Care with Trilaciclib in Patients with Small Cell Lung Cancer [Poster Presentation]. Presented at: American Society of Clinical Oncology (ASCO). May 2020.

[164] Ferrarotto R, Anderson I, Medgyasszay B, et al. Trilaciclib reduces the need for growth factors and red blood cell transfusions to manage chemotherapy-induced myelosuppression. [Oral Presentation]. Presented at: North America Conference on Lung Cancer, October 2020. *https://naclc2020.iaslc.org/program-at-a-glance/.*

[165] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Summary No. K1191114. 2019. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191114.pdf.*

these MS–DRGs appear to be MS–DRGs 264, 356, 357, 358, 628, 629, 630, 673, 674, 675, 907, 908, 909, 981, 982, and 983. With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant generally stated that Ellipsys will be used to treat the same or similar type of disease and the same or similar patient population as the current standard-of-care treatments.

In summary, the applicant believes that Ellipsys is not substantially similar to other currently available therapies and/or technologies because it uses a new mechanism of action and that therefore, the technology meets the ''newness'' criterion. However, we believe that the mechanism of action for Ellipsys may be the same or similar to the original version of the Ellipsys system, which received FDA approval on June 22, 2018. Though the current IFU includes an additional procedure as part of the index procedure, it is not clear that this step of balloon angioplasty done concurrently changes the mechanism of action of the Ellipsys system. Per the FDA's 510(k) summary, compared to the predicate device, there were no changes to the device or the manner in which it creates a percutaneous anastomosis, and other than the additional procedural step of balloon dilation, all characteristics remain unchanged.[166] In addition, clinicians were not precluded from performing this step before the change in the IFU, and in fact, balloon dilation was already performed during the index procedure in some cases.[167] Though the applicant maintains that performing this additional step in all cases, as opposed to some, leads to superior clinical outcomes, we are unclear if this has any bearing on newness for this technology or if it represents a change in the mechanism of action of this device. We note that if the current device is substantially similar to the original version of Ellipsys, we believe the newness period for this technology would begin on June 22, 2018 with the De Novo approval date and, therefore, because the 3-year anniversary date of the technology's entry onto the U.S. market (June 22, 2021) would occur in FY 2021, the technology would no longer be considered new and would not be eligible for new technology add-on payments for FY 2022. We welcome public comments on whether the change in the Ellipsys IFU represents a change to the device's mechanism of action.

We also note that differences in mechanism of action between Ellipsys and WavelinQ were not included. We note that CMS stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58702) that WavelinQ uses a unique mechanism of action that differed from that of other commercially available devices.

We are inviting public comments on whether Ellipsys is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion.

The applicant searched the FY 2019 MedPAR claims data file with the FY 2019 IPPS/LTCH PPS final rule correction notice IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using the Ellipsys. The applicant stated that currently, there are two ICD–10–PCS procedure codes that describe percutaneous AVF in the radial artery: 031B3ZF (Bypass right radial artery to lower arm vein, percutaneous approach) and 031C3ZF (Bypass left radial artery to lower arm vein, percutaneous approach). The applicant stated that these codes are not specific to percutaneous AVF formation using thermal energy. We note that the applicant submitted a request for approval for a unique ICD–10–PCS code for the use of the Ellipsys beginning FY 2022. The applicant stated that if the procedure were reported with the previously mentioned procedure codes, Ellipsys would be mapped to the following MS–DRGs:

MS-DRG	Title
264	Other Circulatory System O.R. Procedures
356	Other Digestive System O.R. Procedures with MCC
357	Other Digestive System O.R. Procedures with CC
358	Other Digestive System O.R. Procedures without CC/MCC
628	Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC
629	Other Endocrine, Nutritional and Metabolic O.R. Procedures with CC
630	Other Endocrine, Nutritional and Metabolic O.R. Procedures without CC/MCC
673	Other Kidney and Urinary Tract Procedures with MCC
674	Other Kidney and Urinary Tract Procedures with CC
675	Other Kidney and Urinary Tract Procedures without CC/MCC
907	Other O.R. Procedures For Injuries with MCC
908	Other O.R. Procedures For Injuries with CC
909	Other O.R. Procedures For Injuries without CC/MCC
981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC
982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC
983	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC/MCC

The applicant added that ICD–10 codes 031B3ZF and 031C3ZF were new effective October 1, 2019 and therefore do not appear in the 2019 claims data. According to the applicant, the most common MS–DRGs for patients admitted with chronic kidney disease and who received an open procedure for creation of an AVF are shown below.

[166] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. 510(k) Summary No. K1191114. 2019. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191114.pdf.*

[167] Hull JE, Jennings W, *et al.,* ''The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access,'' *Journal of Vascular and Interventional Radiology* 2018; 29: 149–158.

MS-DRG	Title
264	Other Circulatory System O.R. Procedures
673	Other Kidney and Urinary Tract Procedures w MCC
674	Other Kidney and Urinary Tract Procedures w CC
252	Other Vascular Procedures w MCC
628	Other Endocrine, Nutritional and Metabolic O.R. Procedures w MCC

The applicant has not made a request for Ellipsys to be mapped to a new MS–DRG for FY 2022.

The applicant stated that claims which had a diagnosis code for Chronic Kidney Disease (CKD) stage IV, CKD stage V, or ESRD and which included an open bypass of the subclavian artery to upper arm vein or the radial artery to lower arm vein during the same stage were included in the cost analysis. The applicant stated they used the following ICD–10 codes in their analysis to identify claims.

Codes	Description
ICD-10-CM Diagnosis Codes	
N18.4	Chronic kidney disease, stage 4
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
ICD-10-PCS Procedure Codes	
03130ZD	Bypass right subclavian artery to upper arm vein, open approach
03140ZD	Bypass left subclavian artery to upper arm vein, open approach
031B0ZF	Bypass right radial artery to lower arm vein, open
031B3ZF	Bypass right radial artery to lower arm vein, perc
031C0ZF	Bypass left radial artery to lower arm vein, open
031C3ZF	Bypass left radial artery to lower arm vein, perc

Cases mapping to the top five MS–DRGs by volume were selected, which resulted in 689 cases or 79% of case volume.

The applicant determined an average unstandardized case weighted charge per case of $91,190.

The applicant did not remove charges for prior technology because the cases identified included an open procedure that is not performed using a specific device. However, the applicant stated that all charges for the operating room (OR) were removed as the procedures involving the technology would not always be performed in an OR. The applicant stated that departmental charges were standardized using the factors from the standardization file released with the FY 2021 final rule. The applicant then standardized the charges using the FY 2019 Final Rule with Correction Notice Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the technology, the applicant used the national average CCR for the Supplies and Equipment cost center of 0.297 from the FY 2021 IPPS/LTCH PPS final rule. The applicant added charges for other items and services related to the technology; half of the average departmental charges for the OR removed in a prior step were added back to the per case charge, by MS–DRG, as procedures using the technology would sometimes be performed in an OR. The applicant calculated a final inflated average case-weighted standardized charge per case of $119,158, which exceeded the average case-weighted threshold amount of $91,190 by $27,967. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

We note that the applicant used claims with open subclavian artery bypass to upper arm vein, in addition to radial lower arm fistulas, as a proxy for Ellipsys cases. The applicant stated that Ellipsys may provide an alternative to these cases in some instances where AVF placement in the radial arteries is possible but the surgeons are unfamiliar with the procedure. However, we question if these are the most appropriate proxy, as Ellipsys should not replace radiocephalic fistulas, per standard guidelines that recommend wrist fistulas first; and it would be more likely that surgeons would use Ellipsys over upper arm fistulas than a subclavian fistula, which is used rarely in standard practice.

We are inviting public comments on whether the Ellipsys® Vascular Access System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Ellipsys® Vascular Access System represents a substantial clinical improvement over existing technologies. Broadly, the applicant outlined three comparators with respect to which it asserted Ellipsys provides a substantial clinical improvement: (1) Percutaneous AVF with the WavelinQ™ (4F) EndoAVF System; (2) percutaneous AVF (pAVF) with the prior version of Ellipsys; and (3) surgical AVF (sAVF).

With respect to the first comparison, Ellipsys as compared to WavelinQ, the applicant stated that Ellipsys has improved outcomes including technical success and cumulative patency. The applicant cited the following to support superiority of Ellipsys over WavelinQ: (1) Higher fraction of cases with clinically functional AVFs; (2) speedier maturation; (3) more durable AVFs; and (4) smaller failure rate. According to the applicant, no head-to-head clinical trial is available, but they provided one retrospective study that provides a direct comparison between the two pAVF systems to support their claims.

Shahverdyan et al. performed a retrospective review of 100 patients undergoing percutaneous fistula creation at a single site in Germany between December 2017 and December 2019 to compare outcomes with pAVF

creation using the Ellipsys and WavelinQ systems.[168] In this single-operator, comparative case series, 65 Ellipsys procedures and 35 WavelinQ procedures were completed, following a procedure sequence algorithm for selecting the type of vascular access. Per the study, wrist sAVF was the first choice as per standard practice guidelines, followed by proximal forearm pAVF, resulting in 100 pAVFs using Ellipsys (n=65) and WavelinQ (n=35). Demographics for the study patients included 69 percent male and median age of 64.1 years. There were no significant differences between WavelinQ and Ellipsys patients in age, Body Mass Index (BMI), Chronic Kidney Disease (CKD) status, AVF history, or presence of diabetes, though the WavelinQ group had a higher proportion of males. The primary endpoints were technical success, time to maturation, functional patency, and time to first clinical use, and median follow-up was 186.5 days. The study reported technical success, defined as post-procedure ultrasound examination demonstrating a patent anastomosis and fistula flow, with Ellipsys at 100 percent vs. 97 percent with WavelinQ (p=0.35). Interventions were performed in approximately 27 percent of cases for both technologies, and the number of interventions per patient-year was 0.96 vs. 0.46, respectively.

Per the applicant, the study demonstrated a higher fraction of cases with clinically functional AVFs using Ellipsys, as fistula maturation at four weeks was 68.3 percent with Ellipsys vs. 54.3 percent with WavelinQ (p=0.1709), and at the end of the study period, 83.3% and 71.4% respectively. In addition, the applicant stated that successful dialysis access was achieved in 79.5 percent of Ellipsys cases vs. 60.9 percent for WavelinQ cases among patients on dialysis (p=0.0711). The applicant also stated that the study demonstrated that Ellipsys results in speedier maturation with Ellipsys demonstrating a median time to cannulation of 60 days vs. 90 days with WavelinQ (p=0.3676). Next, the applicant stated that use of Ellipsys demonstrated more durable AVFs, with a secondary patency rate (the time from fistula creation to fistula abandonment, including any interventions) at 12 months of 82 percent as compared to 60 percent with WavelinQ, and a functional patency rate of 100% vs 85.7%, respectively. We note that primary patency (the time from fistula creation to the first intervention) between groups was not significantly different. Lastly, access failure occurred in 15.4 percent of Ellipsys patients vs 37.1 percent of WavelinQ patients (p=0.0137), which demonstrated that use of Ellipsys results in a smaller failure rate, according to the applicant.

With regard to the second comparison, Ellipsys compared to the previous version of the technology, the applicant states that since the IFU dated 8/9/19 now states that balloon angioplasty should be performed at the time of the creation procedure, they believe that Ellipsys should be considered a different device. Per the applicant, this subtle difference is of key clinical importance to successful use of Ellipsys, as this method decreases the time to two-needle cannulation (2NC) and also improves initial flow, resolving vascular spasm at the time of the procedure and reducing early thrombosis. The applicant further states that performing balloon angioplasty 100 percent of the time also decreases the number of secondary procedures. To support these claims, the applicant compared results from the Ellipsys pivotal trial that used the earlier IFU, in which angioplasty was performed simultaneously on 19% of patients, with the Ellipsys post-market registry that implemented the change and performed the additional step on 100% of patients.

Ellipsys's pivotal trial was a prospective, single-arm, non-inferiority study of 107 patients at five sites to compare Ellipsys with a 90-day performance goal based on a meta-analysis of surgical results from the literature.[169] Inclusion criteria included vascular anatomy specific to the indications for Ellipsys, age between 18 and 80 years old, and CKD stage IV or V. Exclusion criteria included recent surgery or major illness within 6 weeks, acute or active infection, and use of immunosuppressive medication. Of 261 patients evaluated, a total of 117 met inclusion and exclusion criteria, with 28 percent excluded due to unsuitable anatomy. 107 were included in the intent to treat (ITT) population after each study site completed 2 proctored procedures. Demographics included 73 percent male, mean patient age of 56.7 years, and mean BMI of 31.2 percent. All patients in the ITT population received a pAVF with Ellipsys between the proximal radial artery and perforating vein, followed by separate maturation procedures. The primary efficacy endpoint of the study was maturation success, defined as brachial artery flow volume greater than or equal to 500ml/min and target vein diameter greater than or equal to 4mm in more than 49 percent of patients at 90 days. This performance goal was obtained from a meta-analysis of 8 studies of open sAVF, where the weighted least squares mean success rate was 62 percent, and the lower bound from a 2-sided 95 percent lower confidence interval was 49 percent. The primary safety endpoint was the absence of device-related complications at 90 days. Access failure occurred in 4/107, with a technical success rate of 95 percent. The primary endpoint was met by 86 percent at 90 days (the 97.5 percent lower confidence interval was 77.9 percent), exceeding the 49 percent performance goal (p<0.0001). Cumulative patency was 91.6 percent at 90 days and 86.7 percent at 1 year. During the 12-month study, 88 percent of the patients on hemodialysis (71 of 81) had successful 2-needle cannulation, including 63 patients on dialysis at enrollment and 18 who initiated dialysis during the study. The mean time to cannulation was 114.3 days ± 66.2 (34–345 days). Per the authors, spasm of the perforating vein was easily treated with vasodilators and balloon dilation as a matter of routine care. Nineteen percent of patients (20/107) received balloon dilation during the index procedure, and second stage maturation procedures included 113 balloon dilations in 77 patients. A total of 205 maturation procedures were performed on 99 patients at a mean of 35.1 days. An additional 66 maintenance procedures were performed in 35 patients at a mean of 17 days, for a total of 271 secondary procedures during the 12 months of the study (2.7 per patient year).

The Ellipsys post-market registry by Hull et al. was a prospective single-operator study of 60 patients receiving a pAVF with Ellipsys at a single outpatient US site in an attempt to understand patient selection, maturation, and cannulation with pAVFs.[170] Patient demographics included 57 percent male, mean age of 64, and mean BMI of 30.7. 123 patients with ESRD stages IV and V were evaluated by ultrasound to determine suitability for AVF. Ninety-two percent were eligible for sAVF and 61 percent

[168] Shahverdyan et al., ''Comparison of Outcomes of Percutaneous Arteriovenous Fistulae Creation by Ellipsys and WavelinQ Devices,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1365–1372. (Published on-line August 11, 2020.)

[169] Hull JE, Jennings W, et al., ''The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access,'' *Journal of Vascular and Interventional Radiology* 2018; 29: 149–158.et al.,

[170] Hull JE, Deitrick J, Groome K, ''Maturation for Hemodialysis in the Ellipsys® EndoAVF Post-Market Registry,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1373–1381. (Published on-line August 13, 2020.)

were eligible for pAVF. Of the 95 patients who received an AVF, 63 percent (60) received pAVF and 37 percent (35) received sAVF. All 60 pAVF patients underwent pAVF creation under ultrasound guidance, followed by balloon dilation, as compared to the pivotal trial where only 19 percent had balloon dilation as part of the index procedure. After 4 weeks, maturation and suitability for dialysis were assessed. The fistulas were considered suitable when palpable on examination and the target vein had 500ml/min flow volume and 5mm diameter. Fifty-two additional maturation procedures, including balloon dilation in 62 percent, were performed in 40 of 60 patients to achieve adequate flow volume and diameter in the target vein. Physiologic maturation was achieved in 93 percent (56 of 60 patients) with a mean time of 40.4 days ± 4.3, and of the remaining 4 patients, one thrombosed and three died prior to maturation. In the 54 patients requiring dialysis, 87 percent achieved 2NC at a mean of 76.8 days. Six month cumulative patency and functional patency were both 94 percent. 70 maintenance procedures were performed in 63 percent. Only 2 patients achieved 2NC without an additional procedure. The authors noted that this study is limited by a modest sample size and single-site study with surgeons experienced in pAVF creation, and that results were not compared to surgery.

According to the applicant, the post-market registry demonstrated the significant clinical differences between performing balloon angioplasty as part of the index procedure 19 percent of the time (as seen in the pivotal trial) compared to 100 percent of the time. The results showed that the average time to 2NC decreased from 100 days to 70 days. The study also compared initial AVF flow between the studies, which increased to 649 ml/min from 330.4 ml/min, attributed to the reduction in instances of venospasm due to balloon dilation.[171] According to the study investigators, this decrease in venospasm and higher flow led to a reduction in early thrombosis from 11 percent to 2 percent. Lastly, the applicant compared the number of secondary procedures between the two studies with the following table:

	Maturation Procedures per Patient	Maintenance Procedures per Patient	Total Secondary Procedures per Patient
Pivotal Trial	205/103 = 1.99	66/103 = 0.64	2.63
Maturation Study	52/60 = 0.87	70/60 = 1.17	2.04

Per the applicant, despite the higher standard for maturation in the second study (5mm target vein diameter vs 4mm in the pivotal study), the number of maturation procedures decreased, while maintenance procedures increased. Overall, secondary procedures decreased with the new protocol, as described in the table submitted by the applicant.

With respect to the third comparison, Ellipsys as compared to sAVF, the applicant stated that Ellipsys creates a side-to-side fistula with a percutaneous approach while sAVFs for the most part create end-to-side fistulas. According to the applicant, in patients that have suitable anatomy for pAVF creation, this method of fistula creation contributes to improved outcomes in five ways: (1) Higher fraction of cases with clinically functional AVFs; (2) decreased time to two-needle cannulation; (3) more durable AVFs; (4) decreased need for secondary interventions; and (5) patient satisfaction with Ellipsys AVFs. According to the applicant, no head-to-head studies or randomized trials between Ellipsys and sAVFs are available, and instead, results of key variables of interest were compared using studies with comparable results for sAVFs from published literature. The applicant provided 2 prospective single-arm studies and 5 retrospective studies, including the studies previously discussed, to support these claims. They also submitted data from one unpublished study. Aside from the Ellipsys pivotal trial, the Ellipsys post-market registry, and the comparison study with WavelinQ already summarized, the remaining studies are summarized below.

The 2-year results of the pivotal trial were analyzed retrospectively by Beathard.[172] 105 patients with 2 year follow-up data were included, and of these, 103 had functioning fistulas and all were receiving dialysis except 3. Cumulative patency at 18 and 24 months was 92.8 percent and 91.6 percent, respectively. Patient experience with pAVF was assessed among those who had received a previous access procedure (⅓). When compared to their previous procedure, patients rated Ellipsys as the same in 68 percent, better or much better in 29 percent, and worse in 3 percent. Patients mentioned difficulty with cannulation due to unfamiliarity of dialysis staff with pAVF, but commented on the lack of surgical scar and short recovery time. Among all patients who responded, 93 percent rated their access as very good or excellent.

A retrospective review of 34 patients who received pAVF between May 2017 and November 2018 at a clinic in France was submitted.[173] Patients included had ESRD, were not candidates for wrist fistulas, and met the anatomic criteria for use of Ellipsys. Demographics included patients that were 58 percent male, 65 percent Caucasian and 35 percent African, and a mean age of 62 years old. After fistula creation with Ellipsys, all anastomoses received balloon dilation. Twenty-four of 34 patients had successful 2NC within 6 weeks. Forty-four percent of patients did not require secondary interventions, and 12 percent required additional dilation within 4 weeks to improve maturation. Two patients converted to a surgical fistula due to cannulation difficulties. No patients developed steal syndrome or aneurysmal changes in the one year follow-up period. Study authors noted that one benefit of pAVF over sAVF is the potential for multiple outflow cannulation veins, as compared to a sAVF in the same location, where the median cubital vein is ligated to augment flow into a single vessel.

Another study provided was a retrospective cohort study of 232

[171] Hull JE, Deitrick J, Groome K, ''Maturation for Hemodialysis in the Ellipsys® EndoAVF Post-Market Registry,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1373–1381. (Published on-line August 13, 2020.)

[172] Beathard et al., ''Two-year cumulative patency of endovascular AVF'' JVA 2020; 21: 350–356.

[173] Hebibi et al, ''Clinical hemodialysis experience with percutaneous arteriovenous fistulas created using the Ellipsys® vascular access system,'' *Hemodialysis International* 2019; 23(2): 168–172.

consecutive patients who underwent pAVF creation with Ellipsys at a single center in France.[174] An Ellipsys pAVF was the second choice after a radiocephalic surgical wrist fistula. Patients were 63 percent male, with a mean age of 64 years old (25–92). Balloon angioplasty was considered part of the index procedure and performed in all cases. Technical success was achieved in 99 percent. At 1 year, the primary patency rate was 54 percent and the secondary patency rate was 96 percent with a mean follow up of 252 days. The most frequent intervention (35 percent of patients) was additional balloon angioplasty. Eleven percent of patients underwent procedures for superficialization of deep veins. Average maturation time by clinical or ultrasound criteria was 4 weeks, and successful cannulation was established in less than 2 weeks in 10 percent of patients. No significant adverse events related to the procedures occurred. Three patients (1 percent) required later conversion to sAVF, two due to occlusion of the anastomosis and one due to rupture of the perforator during an angioplasty procedure and pseudoaneurysm. The authors conclude that pAVFs have reduced need for reinterventions and result in a moderate-flow fistula with shared venous drainage. They further state that minimally invasive AVF creation with the low risk of complications seen using Ellipsys can be particularly beneficial in older patients, especially since the lower flow fistula as compared to brachial artery inflow AVFs decreases the risk of cardiac issues. They conclude that large-scale randomized studies are needed to confirm their findings.

In another study, a case series of 14 patients who achieved early cannulation with an Ellipsys pAVF underwent retrospective review at an outpatient department in Europe.[175] In these patients, cannulation within 14 days post creation was performed using plastic cannulas in order to avoid catheter insertion or replacement for dialysis. The procedure was successful in all except one case. Primary patency at 12 months was 66 percent and cumulative patency was 100 percent, with the authors concluding that this success suggests that pAVF could serve as an alternative to catheter for immediate dialysis.

The applicant also submitted preliminary unpublished results from a 3-year follow up of 99 of the pivotal trial patients, stating that while Ellipsys AVFs required more maturation procedures, in the 2 years following creation they required fewer maintenance procedures as compared to results for sAVF reported in the literature, with an average of 0.83 vs. 3.41, respectively. Additionally, they stated that at every follow-up period, Ellipsys showed improved cumulative patency over sAVF results from the literature, with rates of 90 percent vs 46 percent at 36 months.

The applicant summarized results from all of the studies to support each claim of Ellipsys's superiority over sAVF by comparing to historical controls in the literature. For the claim of more clinically functional AVFs, the applicant summarized results from 4 studies, demonstrating 2NC in 88 percent at one year and 95 percent at 2 years, 87 percent with an average follow up of 282 days, and 82 percent within 6 weeks.[176] [177] [178] [179] This was compared to a value of 53.4 percent successful cannulation for sAVF from a study that looked at the effect of age over 65 on clinical outcomes for radiocephalic and brachiocephalic AVF.[180] For the claim of decreased time to 2NC, the applicant summarized the results from 5 studies, demonstrating a mean time to 2NC for Ellipsys of 100.2 days, 65.5 ± 45.7 days, a range of 10 days to 6 weeks, 4 weeks, and 60 days.[181] [182] [183] [184] [185] This was compared to a mean of 136 days for sAVFs, taken from the United States Renal Data System.[186] For the claim of more durable AVFs, the applicant summarized results from 5 studies demonstrating Ellipsys's cumulative patency at 12 months, ranging from 82 percent to 100 percent, and 91.6 percent at 24 months.[187] [188] [189] [190] The applicant compared these results to a patency rate of 65 percent for sAVFs found in the USRDS database.[191] The applicant further stated that preliminary results from the pivotal trial 3 year follow-up reinforce this claim, as they found that the cumulative patency using Ellipsys was 90 percent at 36 months, compared to a historical value of 46 percent for sAVFs. For the claim of decreased secondary interventions (including maturation and maintenance procedures), the applicant summarized outcomes from 3 studies demonstrating 0.96 secondary interventions per patient year in the study by Shahverdyan et al.; 2.63 interventions per year in the pivotal trial; and an average of 0.83 maintenance inventions per patient in the 2 years following creation in the preliminary results of the 3 year follow-up by Hull et al. The applicant stated that a comparable value for sAVFs is

[174] Mallios et al., ''Mid-term results of percutaneous arteriovenous fistula creation with Ellipsys vascular access system, technical recommendations and an algorithm for maintenance,'' *Journal of Vascular Surgery* 2020; 72(6): 2097–2106. (Published on-line April 7, 2020.).

[175] Mallios et al., ''Early cannulation of percutaneously created AVFs'', *Journal of Vascular Access* 2020; 21(6): 997–1002. (Published on-line December 19, 2019.)

[176] Hull JE, Jennings W, *et al.,* ''The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access,'' *Journal of Vascular and Interventional Radiology* 2018; 29: 149–158.

[177] Beathard GA, *et al.,* ''Two-year cumulative patency of endovascular arteriovenous fistula,'' *Journal of Vascular Access* 2020; 21: 350–356.

[178] Hull JE, Deitrick J, Groome K, ''Maturation for Hemodialysis in the Ellipsys® EndoAVF Post-Market Registry,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1373–1381. (Published on-line August 13, 2020.)

[179] Hebibi H, *et al.,* ''Clinical hemodialysis experience with percutaneous arteriovenous fistulas created using the Ellipsys® vascular access system,'' *Hemodialysis International* 2019; 23(2): 16 8–172.

[180] Weale A, *et al.,* ''Radiocephalic and Brachiocephalic Arteriovenous Fistula Outcomes in the Elderly,'' *Journal of Vascular Surgery* 2008; 47(1): 144–150.

[181] Hull JE, Jennings W, *et al.,* ''The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access,'' *Journal of Vascular and Interventional Radiology* 2018; 29: 149–158.

[182] Hull JE, Deitrick J, Groome K, ''Maturation for Hemodialysis in the Ellipsys® EndoAVF Post-Market Registry,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1373–1381. (Published on-line August 13, 2020.)

[183] Hebibi H, *et al.,* ''Clinical hemodialysis experience with percutaneous arteriovenous fistulas created using the Ellipsys® vascular access system,'' *Hemodialysis International* 2019; 23(2): 168–172.

[184] Mallios A, Bourquelot P, Franco G, *et al.,* ''Mid-term results of percutaneous arteriovenous fistula creation with Ellipsys vascular access system, technical recommendations and an algorithm for maintenance,'' *Journal of Vascular Surgery* 2020; 72(6): 2097–2106. (Published on-line April 7, 2020.)

[185] Shahverdyan R, *et al.,* ''Comparison of Outcomes of Percutaneous Arteriovenous Fistulae Creation by Ellipsys and WavelinQ Devices,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1365–1372. (Published on-line August 11, 2020.)

[186] United States Renal Data System. 2016 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016.

[187] Beathard GA, *et al.,* ''Two-year cumulative patency of endovascular arteriovenous fistula,'' *Journal of Vascular Access* 2020; 21: 350–356.

[188] Mallios A, Bourquelot P, Franco G, *et al.,* ''Mid-term results of percutaneous arteriovenous fistula creation with Ellipsys vascular access system, technical recommendations and an algorithm for maintenance,'' *Journal of Vascular Surgery* 2020; 72(6): 2097–2106. (Published on-line April 7, 2020.)

[189] Shahverdyan R, *et al.,* ''Comparison of Outcomes of Percutaneous Arteriovenous Fistulae Creation by Ellipsys and WavelinQ Devices,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1365–1372. (Published on-line August 11, 2020.)

[190] Mallios A, *et al.,* ''Early cannulation of percutaneously created arteriovenous hemodialysis fistulae,'' *Journal of Vascular Access* 2020; 21(6): 997–1002. (Published on-line December 19, 2019.)

[191] Al-Jaishi, Ahmed A., et al. ''Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta-analysis.'' *American Journal of Kidney Diseases* (2014) 63(3): 464–47.

3.41 over 2 years.[192] Finally, for the claim of patient satisfaction, the applicant cited results of the patient survey performed by Beathard et al., stating that the survey indicated a high level of satisfaction with Ellipsys, with 93 percent rating their access as very good or excellent, and 95 percent rating their lack of pain as very good or excellent. Additionally, patients noted the lack of scar, short recovery time, and ease of use with Ellipsys.[193]

We note that only one of the studies submitted by the applicant in support of a finding of substantial clinical improvement for Ellipsys has a comparator arm (retrospective comparison), and none were created with a methodology to demonstrate superiority. In addition, some studies may be limited by potential bias due to single operator and/or single site design, and comparisons to sAVF were made using various historical controls from different studies with no statistical analyses, making it difficult to account for confounding variables. We further note that the studies used physiologic endpoints as a surrogate outcome for fistula maturity instead of a clinically functional fistula as determined by successful 2-needle cannulation. Of interest, a number of the studies submitted concluded that there is a further need for head-to-head, larger scale, or longer trials to confirm claims of superiority of pAVF over surgical AVF and other pAVF devices. We note that the applicant provided one retrospective study with a small sample size to support the claim of superiority of Ellipsys over WavelinQ. Though this study by Shahverdyan et al. demonstrated numerically better outcomes for multiple endpoints with Ellipsys, we note that outcomes did not reach statistical significance for primary patency, technical success, maturation rates, time to cannulation, or fistula success, and we note the potential for bias with the single operator/single site study design.

We note that the decreased interventions and time to 2NC using Ellipsys were reported from studies performed outside of the US, where practice patterns are different. Per the Hull et al. study, practice in the US is to direct flow into a single upper arm vein to meet established guidelines for fistula flow diameter depth and length, whereas in the European studies, multiple outflow veins were accepted.[194] The authors further state that allowing multiple outflow veins decreases the number of secondary maturation procedures used to direct flow, but requires advanced cannulation techniques, ultrasound guidance, and plastic access cannulas that are not available in the US. These techniques and the use of plastic cannulas also allow for early cannulation of the fistula in European studies. For these reasons, we question whether the European results are generalizable to the US population.

When comparing the new protocol for Ellipsys (always performing balloon angioplasty) to the De Novo protocol (sometimes performing balloon angioplasty), Ellipsys demonstrated a reduced number of maturation procedures and faster time to cannulation; however, more maintenance procedures were required than the De Novo protocol. In addition, the investigators did not account for potential confounding variables between the different studies, which could have affected outcomes in order to compare the two studies used to claim superiority. We further note that previously, balloon angioplasty was nearly always performed, whether as part of the index procedure, as a maturation procedure, or as a maintenance procedure, and it continued to be a necessary secondary intervention after adoption of the new procedural step.

We are inviting public comments on whether the Ellipsys® Vascular Access System demonstrates improvement over each of the three comparators and meets the substantial clinical improvement criterion.

We received public comments in response to the New Technology Town Hall meeting regarding the application of the Ellipsys® Vascular Access System for new technology add-on payments.

Comment: The applicant submitted a public comment providing an additional study and addressing questions posed at the town hall meeting. The study provided is a single-center retrospective comparison article in press of Ellipsys and sAVF by Harika et al. 107 patients who received pAVF with Ellipsys at this center between May 2017 and May 2018 were compared to an equal number of consecutive patients who received a surgical fistula in the same time period. Patients with grafts or lower extremity fistulae were excluded and baseline characteristics and demographics were comparable between groups. All pAVFs were created by a single surgeon, while the sAVFs were created by 4 surgeons. Primary outcomes were primary and secondary patency rates, as well as maturation as determined by AVF utilization, or >4mm diameter and >500ml/lt flow for pre-dialysis patients. Secondary outcomes assessed secondary interventions and rate of complications. Per the applicant, at 6 weeks, pAVF maturation rates were higher compared to the sAVF arm (65 percent vs 50 percent, p=0.01). In addition, primary patency in the sAVF group was higher than pAVF at 12 months (86 percent vs 61 percent, p<0.01) but comparable at 24 months (52 percent vs 55 percent, p=0.48), and secondary patency rates were not significantly different between groups at 12 or 24 months. Rates of secondary interventions were divided between percutaneous and surgical interventions. At 2 years, the rate of percutaneous reinterventions was similar but the sAVFs required more surgical revisions (36% vs. 17%). Differences in total interventions between groups did not reach statistical significance at 12 and 24 months. The study authors conclude that pAVF's better aesthetic result, short procedure time, and ability to perform easily in an outpatient office procedure center indicates that Ellipsys has many benefits, but large prospective randomized multicenter studies are needed to confirm the outcomes demonstrated in this study.[195]

In response to a question regarding the need for a head-to-head comparison between WavelinQ and Ellipsys to determine superiority, the applicant stated that there are no randomized controlled trials available but the study (summarized previously) by Shahverdyan et al. provides a reasonable comparison of the two. Per the applicant, the algorithm to choose which procedure to perform reflected ''real-world'' choices, and the results demonstrated that Ellipsys offers substantial clinical improvement over WavelinQ. In response to a comment questioning the available 2-year data using the current version of Ellipsys, the applicant stated that the 2-year follow up study (Beathard et al.) of the pivotal trial captured results of patients treated with immediate angioplasty, as that was done in 19 percent of patients even

[192] Lee T, *et al.,* ''Long-Term Outcomes of Arteriovenous Fistulas with Unassisted versus Assisted Maturation: A Retrospective National Hemodialysis Cohort Study,'' *Journal on American Nephrology* 2019; 30(11):2209–2218.

[193] Beathard GA, *et al.,* ''Two-year cumulative patency of endovascular arteriovenous fistula,'' *Journal of Vascular Access* 2020; 21: 350–356.

[194] Hull et al., ''Maturation for Hemodialysis in the Ellipsys EndoAVF Post-Market Registry,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1373–1381. (Published on-line August 13, 2020.)

[195] Harika G, et al., ''Comparison of surgical versus percutaneously created arteriovenous hemodialysis fistulae,'' *Journal of Vascular Surgery* 2020; accepted for publication December 5, 2020, in press.

before the procedural change. The applicant further stated that the current version of Ellipsys differs only by the addition of this procedural step, and studies after the pivotal trial adopted this practice to better results, with this combination of results indicating that the balloon angioplasty step improves outcomes over a multi-year period. In addition, the applicant stated that the Harika et al. study (summarized previously) had a 2-year study period, and all patients had immediate balloon angioplasty. In response to a question regarding the comparability of pAVF in the proximal radial artery with a sAVF in the same location, the applicant stated though they are created differently, they are functionally comparable once mature, and neither typically requires superficialization.

Next, in response to a question regarding what the fewer short-term complications using Ellipsys are as compared to sAVF, the applicant stated that these include lower wound morbidity due to minimal incisions, fewer aneurysms, avoidance of vasospasm, and lower incidence of clinically significant steal syndrome. The applicant stated that in sAVF, clinically significant steal syndrome can occur in as many as 11 percent of cases, but it is rare in reports of pAVFs placed with Ellipsys. The applicant summarized information on complications with Ellipsys from the studies previously discussed and stated that (1) Harika et al [196] reported that sAVFs had a substantially higher rate of wound healing and infections, as well as more occurrences of steal syndrome and aneurysm; (2) Hull et al's prospective safety and efficacy study [197] examined possible complications in detail and most complications did not appear at all; (3) the Ellipsys pivotal trial [198] reported no complications due to vessel perforation, dissection, or distal embolization were reported; (4) in the Hull et al. Maturation Study,[199] several adverse events were reported including one hematoma, one arm swelling, and one case of steal syndrome; and (5) Mallios et al's report on mid-term results [200] reported no complications, other than cases treated with balloon angioplasty and one case of arm swelling.

The applicant also addressed a final question in its public comment regarding the definition of improved durability. The applicant stated that this is an umbrella term used to reflect the useful life of an AVF for dialysis, and can include different patency measures.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for the Ellipsys® Vascular Access System. With regard to the Harika et al. study provided, we note that prespecified subgroup analyses of pAVF vs elbow fistulae (e-AVF) and pAVF vs wrist fistulae were also compared, with elbow fistula considered to be the most similar comparator to ''real world'' vascular access practice patterns. When comparing outcomes between e-AVF and p-AVF groups in this study, differences in total interventions, maturation at 6 weeks, and secondary patency rates were not significantly different. e-AVF also demonstrated higher 12 month primary patency (p=0.02). We further note that though the applicant asserted that Ellipsys decreases the need for secondary interventions as compared to sAVF, this study did not demonstrate a statistically significant difference between arms for total interventions at 12 or 24 months, and we are concerned that this may not demonstrate a substantial clinical improvement for Ellipsys over sAVF.

Comment: Another public comment was submitted in response to the Town Hall meeting. The commenter stated that during the FY 2022 New Technology Town Hall Meeting, Avenu Medical relied upon a single published study to support claims of substantial clinical improvement for Ellipsys over WavelinQ. Per the commenter, this study indicated that limitations of the review include those of any retrospective analysis on nonrandomized data and possible selection bias.[201] Per the commenter, the authors of the study concluded that both of the devices had high technical success rates and adequate flow volumes, as well as no significant difference in primary patency, and that the devices may serve different patient populations, since patients can be anatomically eligible for one or the other. The commenter concludes that it is important that both technologies are available as treatment options for Medicare beneficiaries and they believe CMS should consider new technology add-on payments for the two pAVF systems together. They also stated that CMS should designate a new technology add-on payment category for devices used in percutaneous creation of an AVF.

Response: We thank the commenter for their input and will take this information into consideration when deciding whether to approve new technology add-on payments for the Ellipsys® Vascular Access System. We note that we are unclear with regard to the commenter's request for a new technology add-on payment category, as the IPPS payment system does not utilize categories, and this request may be referring to another payment system.

g. ENSPRYNG™ (satralizumab-mwge)

Genentech, Inc. submitted an application for new technology add-on payments for the ENSPRYNG™ (satralizumab-mwge) injection (ENSPRYNG) for FY 2022. According to the applicant, ENSPRYNG is indicated by the FDA for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. ENSPRYNG is the first subcutaneous, first self-administered, and third FDA-approved drug for the treatment of this severe chronic autoimmune disease of the central nervous system.[202] The applicant states, due to the severity of relapses, relapse prevention is a key disease management priority. Patients who relapse are often admitted to the hospital for acute treatment. According to the applicant, with every relapse, patients are at risk of becoming blind or paralyzed, and thus it is critical to minimize the risk of future relapses by initiating maintenance treatment with a therapy such as ENSPRYNG in a timely manner while the patient is still

[196] Harika G, et al., ''Comparison of surgical versus percutaneously created arteriovenous hemodialysis fistulae,'' *Journal of Vascular Surgery* 2020; accepted for publication December 5, 2020, in press.

[197] Hull JE, Elizondo-Riojas G, *et al.,* ''Thermal resistance anastomosis device for the percutaneous creation of arteriovenous fistulae for hemodialysis,'' *Journal of Vascular and Interventional Radiology* 2017; 28: 380–387.

[198] Hull JE, Jennings W, *et al.,* ''The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access,'' *Journal of Vascular and Interventional Radiology* 2018; 29: 149–158.

[199] Hull et al., ''Maturation for Hemodialysis in the Ellipsys EndoAVF Post-Market Registry,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1373–1381. (Published on-line August 13, 2020.)

[200] Mallios et al., ''Mid-term results of percutaneous arteriovenous fistula creation with Ellipsys vascular access system, technical recommendations and an algorithm for maintenance,'' *Journal of Vascular Surgery* 2020; 72(6): 2097–2106. (Published on-line April 7, 2020.)

[201] Shahverdyan R., et al. ''Comparison of Outcomes of Percutaneous Arteriovenous Fistulae Creation by Ellipsys and WavelinQ Devices,'' *Journal of Vascular and Interventional Radiology* 2020; 31(9): 1365–1372. (Published on-line August 11, 2020.)

[202] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020. SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019. UPLIZNA (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc.; 2020.

admitted. Therefore, according to the applicant, ENSPRYNG should be approved for new technology add-on payments in order to maximize the likelihood that this especially sick patient population can start the treatment they need while in the inpatient setting.

According to the applicant, NMOSD is a rare, inflammatory, potentially life-threatening autoimmune central nervous system (CNS) disorder characterized primarily by severe, unpredictable relapses of optic neuritis and/or acute longitudinally extensive transverse myelitis (LETM).[203] The applicant asserts that NMOSD has an estimated prevalence of 0.1–10 per 100,000 individuals, affecting nearly 15,000 individuals in the United States.[204] NMOSD occurs in children [205] and adults [206] of all races [207] and disproportionately affects African and Asian females aged 30 to 40 years.[208] According to the applicant, the (bilateral) optic neuritis and/or LETM that are characteristic of NMOSD result from inflammation of the optic nerve, spinal cord,[209] and brainstem,[210] but other regions of the CNS may be affected as well. The vast majority of patients (80%–90%) experience repeated relapses, and disability accumulates with each relapse.[211] Around 60% of patients relapse within one year of diagnosis, and 90% relapse within 3 years.[212] Compared with patients who experience an isolated attack, patients with relapsing disease have greater disease-related clinical burden, and upward of 83% of patients do not fully recover after subsequent relapses.[213]

According to the applicant, the negative impact of NMOSD on patient quality of life (QoL) is predominantly a result of physical disability, pain, vision impairment, and bowel and bladder dysfunction.[214] Disease-induced disability and symptoms have a considerable impact on patients' ability to work and thrive in social activities and personal relationships.[215] The applicant added that the loss of motor and sensory function leads to approximately 50% of patients requiring a wheelchair [216] and 62% of patients becoming functionally blind [217] within 5 years of diagnosis.[218] Therefore, according to the applicant, it is critical that treatments that consistently and effectively reduce the risk of relapse are initiated rapidly in patients diagnosed with NMOSD.

With respect to the newness criterion, ENSPRYNG received FDA BLA approval on August 14, 2020. The applicant added that ENSPRYNG was granted Fast Track designation [219] and Breakthrough Therapy designation [220] by the FDA. The applicant stated that ENSPRYNG was not commercially available until August 24, 2020 because the applicant had to wait for final approval for printing and labeling as well as customs and importation. The recommended loading dosage of ENSPRYNG for the first three administrations is 120 mg by subcutaneous injection at Weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every four weeks. The applicant submitted a request for an ICD–10–PCS code to uniquely identify the administration of ENSPRYNG beginning FY 2022.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposed of new technology add-on payments. The applicant stated that there are limited treatment guidelines available for NMOSD with the most recent US guidelines published in 2012. These US NMOSD treatment guidelines exclusively recommend off-label drugs: Azathioprine, with or without prednisone; mycophenolate mofetil, with or without prednisone; rituximab; or prednisone alone.[221] The applicant stated that there are presently two other FDA-approved therapies for patients with AQP4-IgG positive NMOSD: SOLIRIS (eculizumab),[222] which was approved in 2019, and UPLIZNA (inebilizumab-cdon), which was approved in 2020.[223]

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the application stated that ENSPRYNG is an interleukin-6 (IL–6) receptor antagonist indicated for the treatment of NMOSD in adult patients who are AQP4-IgG positive.[224] According to the applicant, ENSPRYNG targets soluble and membrane-bound IL–6 receptors to inhibit IL–6 signaling and subsequently disrupt downstream inflammatory

[203] Jarius S, Ruprecht K, Wildemann B, et al. Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: A multicentre study of 175 patients. J. Neuroinflammation 2012;9(1) doi:10.1186/1742–2094–9–14.

[204] Flanagan EP, Cabre P, Weinshenker BG, et al. Epidemiology of Aquaporin-4 Autoimmunity And Neuromyelitis Optica Spectrum. Ann Neurol. 2016;79(5):775–783. doi:10.1002/ana.24617.

[205] Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorder (NMOSD). *https://wearesrna.org/living-with-myelitis/disease-information/neuromyelitis-optica-spectrum-disorder/diagnosis/#nmosd.* Accessed August 19, 2020.

[206] Etemadifar M, Nasr Z, Khalili B, Taherioun M, Vosoughi R. Epidemiology of Neuromyelitis Optica in the World: A Systematic Review and Meta-analysis. Mult Scler Int. 2015;2015:174720. doi:10.1155/2015/174720.

[207] Simon KC, Schmidt H, Loud S, Ascherio A. Risk Factors For Multiple Sclerosis, Neuromyelitis Optica And Transverse Myelitis. Mult Scler. 2015;21(6):703–709. doi:10.1177/1352458514551780.

[208] Wingerchuk DM, Lennon VA, Lucchinetti CF, et al. The spectrum of neuromyelitis optica. Lancet Neurol. 2007;6(9)805–815. doi:10.1016/s1474–4422(07)70216–8.

[209] Siegel Rare Neuroimmune Association. Neuromyelitis Optica Spectrum Disorder (NMOSD). *https://wearesrna.org/living-with-myelitis/disease-information/neuromyelitis-optica-spectrum-disorder/diagnosis/#nmosd.* Accessed August 19, 2020.

[210] National Organization for Rare Disorders (NORD®). Neuromyelitis Optica Spectrum Disorder. *https://rarediseases.org/rare-diseases/neuromyelitis-optica/.* Accessed August 19, 2020.

[211] Wingerchuk DM. Diagnosis and Treatment of Neuromyelitis Optica. Neurologist 2007;13(1)2–11. doi:10.1097/01.nrl.0000250927.21903.f8.

[212] Wingerchuk DM, Lennon VA, Lucchinetti CF, et al. The spectrum of neuromyelitis optica. Lancet Neurol. 2007;6(9)805–815. doi:10.1016/s1474–4422(07)70216–8.

[213] Jarius S, Ruprecht K, Wildemann B, et al. Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: A multicentre study of 175 patients. J. Neuroinflammation 2012;9(1) doi:10.1186/1742–2094–9–14.

[214] Beekman J, Keisler A, Pedraza O, et al. Neuromyelitis optica spectrum disorder. Neurol.–Neuroimmunol. Neuroinflammation 2019;6(4)e580. doi:10.1212/nxi.0000000000000580.

[215] Ibid.

[216] Kessler RA, Mealy MA, Levy M. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. Curr. Treat. Options Neurol. 2015;18(1) doi:10.1007/s11940–015–0387–9.

[217] Wingerchuk DM, Hogancamp WF, O'Brien PC, et al. The clinical course of neuromyelitis optica (Devic's syndrome). Neurology 2012;53(5)1107–1107. doi:10.1212/wnl.53.5.1107.

[218] Wingerchuk DM, Weinshenker BG. Neuromyelitis optica: Clinical predictors of a relapsing course and survival. Neurology 2012;60(5)848–853. doi:10.1212/01.wnl.0000049912.02954.2c.

[219] US Department of Health and Human Services. FDA Approves Treatment for Rare Disease Affecting Optic Nerves, Spinal Cord. *https://www.fda.gov/news-events/press-announcements/fda-approves-treatment-rare-disease-affecting-optic-nerves-spinal-cord.* Accessed September 10, 2020.

[220] Genentech, USA Inc. FDA Approves Genentech's Enspryng for Neuromyelitis Optica Spectrum Disorder. *https://www.gene.com/media/press-releases/14873/2020-08-14/fda-approves-genentechs-enspryng-for-neu.* Accessed September 10, 2020.

[221] Kimbrough DJ, Fujihara K, Jacob A, et al. Treatment of Neuromyelitis Optica: Review And Recommendations. Mult Scler Relat Disord. 2012;1(4):180–187. doi:10.1016/j.msard.2012.06.002.

[222] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[223] UPLIZNA (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc.; 2020.

[224] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

effects that contribute to the pathophysiology of NMOSD; [225] ENSPRYNG dissociates from the IL–6 receptor at an acidic pH within endosomes and is recycled to circulation, prolonging the plasma half-life of the drug.[226]

The applicant next identified other drugs used to treat NMOSD and their corresponding mechanisms of action. According to the applicant, these current treatments include: SOLIRIS, for which a precise mechanism of action is unknown but is presumed to involve inhibition of AQP4-IgG-induced terminal complement C5b-9 deposition; [227] UPLIZNA, for which a precise mechanism of action is unknown but is presumed to involve binding to CD19, a surface antigen present on pre-B and mature B cells; [228] azathioprine, for which a precise mechanism of action is unknown; [229] Rituxan, which targets CD20 antigen on B cells and leads to profound B cell depletion, principally over an antibody-dependent cell cytotoxicity mechanism; [230] mycophenolate mofetil, which is an immunosuppressive and an inhibitor of inosine monophosphate dehydrogenase and therefore of the guanosine nucleotide synthesis pathway upon which T and B cells depend; [231] and prednisone, which is a synthetic adrenocortical steroid drug with predominately corticosteroid properties.[232] The applicant concluded that none of these current drugs are characterized by their binding and blocking of soluble and membrane-bound IL–6 receptors to inhibit IL–6 signaling. Therefore, the applicant believes ENSPRYNG has a unique and distinct mechanism of action.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant acknowledged that ENSPRYNG may be assigned to the same MS–DRG when compared to existing technology. Per the applicant, cases representing patients who may be eligible for treatment with ENSPRYNG map to MS–DRGs 058, 059, and 060. With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the use of ENSPRYNG may not involve the treatment of the same or similar patient population when compared with an existing technology because: (1) Current technologies such as SOLIRIS may be contraindicated in patients with unresolved serious *Neisseria meningitidis* infections; and (2) SOLIRIS and UPLIZNA are administered as IV infusions which not all patients may be willing to receive.

In summary, the applicant asserts ENSPRYNG meets the newness criterion because it is the only treatment for NMOSD that works specifically by suppressing IL–6 signaling, and because it may not involve the treatment of the same or similar patient population as existing technology. We note that the applicant states that the use of ENSPRYNG may not involve treatment of the same or similar patient population when compared to SOLIRIS with regard to the treatment of patients with unresolved serious *Neisseria meningitidis* infection and with regard to the treatment of patients unwilling to receive an IV infusion. However, we question if UPLIZNA may also be a treatment option for patients with meningococcal disease. We further question whether patients who are unwilling to receive an IV infusion would constitute a new patient population for NMOSD. We invite public comment on whether ENSPRYNG involves the treatment of the same or similar patient population when compared to existing technologies.

We are inviting public comments on whether ENSPRYNG is substantially similar to other technologies and whether ENSPRYNG meets the newness criterion. With regard to the cost criterion, the applicant provided two cost analyses, with the first being an update of the analysis used in FY 2021 by the applicant for SOLIRIS, which is also indicated for NMOSD, and the second which is specific to ENSPRYNG.

Under the first analysis, the applicant searched the FY 2019 MedPAR database for cases reporting ICD–10–CM code G36.0 in the primary and/or admitting position, which resulted in 583 cases. The applicant imputed one case where an MS–DRG had a case volume lower than 11, resulting in 556 cases mapping to 30 MS–DRGs. The applicant stated that it restricted the analysis to MS–DRGs 058, 059, and 060, which accounted for 92.1% of all cases identified. The applicant also excluded cases that were not included in the FY 2021 Proposed Rule Impact File from this analysis, resulting in a final case count of 466 cases mapping to three MS–DRGs. Using a CCR of 0.343 (national other services average CCR), the applicant then removed all charges in the drug cost center, all charges in the blood cost center, and an additional $12,000 of cost for plasma exchange procedural costs for cases with non-zero charges in the blood cost center, for charges for related and prior technologies. The applicant applied an inflation factor of 13.1%, which per the applicant is the outlier charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule, to update the standardized charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59038), which would have increased the inflated charges. Finally, the applicant added charges for the technology by multiplying the cost of ENSPRYNG, based on an average of 1.22 doses per patient, by the inverse of the national average drug CCR of 0.187 from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant calculated a final inflated average case-weighted standardized charge per case of $150,154, which exceeds the case-weighted threshold of $47,813.

For the second analysis, the applicant used the same sample of cases (466) from the first analysis, as identified in the FY 2019 MedPAR database with the ICD–10–CM code G36.0 and with the same sample restrictions. In this analysis, the applicant did not remove charges for related or prior technologies because, per the applicant, ENSPRYNG is anticipated to neither replace plasma exchange nor be used as a monotherapy in all patients. The applicant standardized and inflated the charges, as well as added charges for ENSPRYNG using the same methodology as the first analysis, described previously. The applicant calculated a final inflated

[225] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[226] Igawa T, Ishii S, Tachibana T, et al. Antibody Recycling By Engineered Ph-Dependent Antigen Binding Improves The Duration of Antigen Neutralization. Nat Biotechnol. 2010;28(11):1203–1207. doi:10.1038/nbt.1691. Heo Y. Satralizumab: First Approval. Drugs 2020;80(14)1477–1482. doi:10.1007/s40265–020–01380–2.

[227] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[228] UPLIZNA (inebilizumab) [prescribing information]. Gaithersburg, MD: Viela Bio, Inc.; 2020.

[229] IMURAN (azathioprine) [prescribing information]. Roswell, GA: Sebela Pharmaceuticals Inc.; 2018.

[230] RITUXAN (rituximab) [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2019.

[231] Allison AC, Eugui EM. Mycophenolate Mofetil And Its Mechanisms of Action. Immunopharmacology 2000;47(2–3)85–118. doi:10.1016/s0162–3109(00)00188–0.

[232] RAYOS (prednisone) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA, Inc.; 2019.

average case-weighted standardized charge per case of $175,021, which exceeded the case-weighted threshold of $47,813. The applicant asserted that ENSPRYNG meets the cost criterion based on these analyses.

Based on the information provided by the applicant, it is uncertain to us why the national other services average CCR was used to inflate costs to charges in the first analysis when the applicant indicated that it removed charges from the drugs cost center and blood cost center. We are seeking public comment on whether this or another CCR, such as a CCR for drugs or blood and blood products, would be more appropriate. Furthermore, in the event that a MS–DRG has fewer than 11 cases, the applicant should impute a minimum case number of 11. We are inviting public comments on whether ENSPRYNG meets the cost criterion, including whether the use of another CCR would substantially alter the results of the applicant's analysis.

With regard to the substantial clinical improvement criterion, the applicant asserts that ENSPRYNG represents a substantial clinical improvement in the following ways: (1) It significantly improves clinical outcomes relative to services or technologies previously available for the treatment of NMOSD in adult patients who are AQP4-IgG positive; (2) these improvements are not accompanied by serious safety concerns; (3) ENSPRYNG is the only FDA-approved treatment for NMOSD that is subcutaneously administered; [233] and (4) the totality of circumstances demonstrates ENSPRYNG, relative to technologies previously available, substantially improves the treatment of Medicare beneficiaries. The applicant submitted two recent studies to support their claims of substantial clinical improvement over existing technologies.

The SAkuraStar (NCT02073279) [234] study was a Phase 3, double-blind, placebo-controlled, parallel-group trial at 44 investigational sites in 13 countries to assess the safety and efficacy of ENSPRYNG monotherapy in patients with NMOSD. 95 (57%) of 168 screened participants aged 18–74 years with AQP4-IgG positive or negative NMOSD met the inclusion criteria and were randomly assigned (2:1) to treatment with ENSPRYNG 120mg (n=63) or visually matched placebo (n=32). Inclusion criteria included participants who had experienced at least one documented NMOSD attack or relapse in the previous 12 months and had a score of 6.5 or less on the Expanded Disability Status Scale, while exclusion criteria included clinical relapse 30 days or fewer before baseline. The primary endpoint was time to the first protocol-defined relapse, based on the intention-to-treat (ITT) population (AQP4-IgG positive and negative) (n=95), and analyzed with stratification for two randomization factors (previous therapy for prevention of attacks and nature of the most recent attack). Treatment in both arms was given subcutaneously at weeks 0, 2, 4, and every 4 weeks thereafter. The double-blind phase was due to last until 44 protocol-defined relapses occurred or 1.5 years after random assignment of the last patient enrolled, whichever occurred first. Participants could enter an open-label phase after the occurrence of a protocol-defined relapse or at the end of the double-blind phase. Protocol-defined relapses occurred in 19 (30%) patients receiving satralizumab and 16 (50%) receiving placebo (hazard ratio 0.45, 95% CI 0.23–0.89; p=0.018). 473.9 adverse events per 100 patient-years occurred in the satralizumab group and 495.2 per 100 patient-years in the placebo group. The authors noted that the incidence of serious adverse events and adverse events leading to withdrawal was similar between groups.

According to the applicant, this study demonstrated that the time to the first relapse was significantly longer in ENSPRYNG-treated patients compared with patients who received a placebo (risk reduction, 55%; hazard ratio, 0.45 (95% CI 0.23, 0.89); p = 0.0184). In the AQP4-IgG positive population, there was a 74% risk reduction and a hazard ratio of 0.26 (95% CI 0.11, 0.63; p = 0.0014). The results in the subgroup of AQP4-IgG negative patients were not statistically significant.[235] [236] The annualized relapse rate for AQP4-IgG positive patients was 0.1 (95% CI, 0.05–0.2) in the ENSPRYNG group and 0.5 (95% CI, 0.3–0.9) in the placebo group.[237] The proportion of relapse-free AQP4-IgG positive patients at week 96 was 77% in the ENSPRYNG group and 41% in the placebo group.[238] According to the applicant, the study concluded that ENSPRYNG monotherapy reduced the rate of NMOSD relapse compared with placebo in the overall trial population and had a favorable safety profile.

In the second Phase 3, randomized, double-blind, placebo controlled study submitted by the applicant, the SAkuraSky (NCT02028884) [239] trial, 83 patients with NMOSD who were seropositive or seronegative for AQP4-IgG were randomly assigned (1:1) to receive either 120 mg of satralizumab (n=41) or placebo (n=42) administered subcutaneously at weeks 0, 2, and 4 and every 4 weeks thereafter, in addition to stable IST. The primary end point was the first protocol-defined relapse in a time-to-event analysis. Key secondary end points were the change from baseline to week 24 in the visual-analogue scale (VAS) pain score (range, 0 to 100, with higher scores indicating more pain) and the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT–F) score (range, 0 to 52, with lower scores indicating more fatigue). Safety was also assessed.

The results of the SAkuraSky trial demonstrated that the median treatment duration with satralizumab in the double-blind period was 107.4 weeks. Relapse occurred in 8 patients (20%) receiving satralizumab and in 18 (43%) receiving placebo (hazard ratio, 0.38; 95% confidence interval [CI], 0.16 to 0.88). Multiple imputations for censored data (including patients who discontinued the trial, received rescue therapy, had a change in baseline treatment, or were continuing in the

[233] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[234] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[235] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020. Traboulsee A, et al. Efficacy of satralizumab monotherapy in prespecified subgroups of SAkuraStar, a phase 3 study in patients with neuromyelitis optica spectrum disorder. Oral Presentation at: Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum; West Palm Beach, FL, USA; February 27–29, 2020.

[236] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020. Traboulsee A, et al. Efficacy of satralizumab monotherapy in prespecified subgroups of SAkuraStar, a phase 3 study in patients with neuromyelitis optica spectrum disorder. Oral Presentation at: Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum; West Palm Beach, FL, USA; February 27–29, 2020.

[237] Traboulsee A, et al. Efficacy of satralizumab monotherapy in prespecified subgroups of SAkuraStar, a phase 3 study in patients with neuromyelitis optica spectrum disorder. Oral Presentation at: Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum; West Palm Beach, FL, USA; February 27–29, 2020.

[238] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[239] US Department of Health and Human Services. Active Study √ Neuromyelitis Optica Spectrum Disorder. *https://clinicaltrials.gov/ct2/results?cond=&term=NCT02028884&cntry=&state=&city=&dist=*. Accessed August 14, 2020.

trial at the data-cutoff date) resulted in hazard ratios ranging from 0.34 to 0.44 (with corresponding P values of 0.01 to 0.04). Among the 55 AQP4-IgG–seropositive patients, relapse occurred in 11% of those in the satralizumab group and in 43% of those in the placebo group (hazard ratio, 0.21; 95% CI, 0.06 to 0.75); among 28 AQP4-IgG–seronegative patients, relapse occurred in 36% and 43%, respectively (hazard ratio, 0.66; 95% CI, 0.20 to 2.24). The between-group difference in the change in the mean VAS pain score was 4.08 (95% CI, −8.44 to 16.61); the between-group difference in the change in the mean FACIT–F score was −3.10 (95% CI, −8.38 to 2.18). The rates of serious adverse events and infections did not differ between groups.

In support of the applicant's claim that ENSPRYNG significantly improves clinical outcomes relative to services or technologies previously available for the treatment of NMOSD in adult patients who are AQP4-IgG positive, the applicant stated that patients treated with ENSPRYNG plus IST exhibited a significantly longer time to first relapse when compared to placebo. This also included a risk reduction of 62% in patients treated with ENSPRYNG plus IST when compared with patients who received a placebo plus IST and a 79% risk reduction in the AQP4-IgG positive population. Results in the AQP4-IgG negative patient subgroup were not statistically significant.[240] The proportion of relapse free AQP4-IgG positive patients at week 96 was 92% in ENSPRYNG plus IST group and 53% in the placebo plus IST group.[241]

According to the applicant's second claim, substantial improvements in clinical efficacy are not accompanied by serious concerns. In the SAkuraSky trial, 90% of patients in the ENSPRYNG plus IST group had at least one adverse event compared to 95% in the placebo plus IST group.[242] The safety profile of ENSPRYNG in the OST period was consistent with the double-blind period. There were no deaths or anaphylactic reactions, rates of AEs and serious AEs did not increase with longer exposure to ENSPRYNG; and the most frequently reported AEs in the OST period were consistent with the double-blind period.[243]

The applicant's third claim concerns the flexibility provided to patients by the option to self-administer ENSPRYNG. According to the applicant, ENSPRYNG is the only FDA-approved treatment for NMOSD that is administered subcutaneously.[244] Once treatment is initiated during inpatient hospital admission, upon discharge and having received adequate training on how to perform the injection, an adult patient/caregiver may administer all subsequent doses of ENSPRYNG at home if the treating physician determines that it is appropriate and the adult patient/caregiver can perform the injection technique. According to the applicant, self-administration provides the patient the option to continue the therapy initiated in the hospital while in the convenience of their own home, with reduced disruption to daily life. The applicant states that additionally, the option to self-administer provides flexibility to patients, as they can bring their medication with them while traveling without having to worry if there is an infusion site nearby. The applicant claims this may potentially reduce the rate of hospital readmissions.

In their fourth claim, the applicant states the totality of circumstances otherwise demonstrate that ENSPRYNG, relative to technologies previously available, substantially improves the treatment of Medicare beneficiaries. The applicant asserts that a cross trial comparison between ENSPRYNG and SOLIRIS (approved for new technology add-on payment in FY 2021) cannot be made due to differences in trial design and study population. However, the applicant noted the following distinctions between ENSPRYNG and SOLIRIS and their clinical trials. Per the applicant, the first distinction is that in the registrational study for SOLIRIS, a higher proportion of patients receiving SOLIRIS than those receiving a placebo discontinued their participation in the clinical trial (17% vs 6%).[245] During the double-blind period of SAkuraSky trial, however, a total of three patients (7%) in the ENSPRYNG group and 10 patients (24%) in the placebo group discontinued the trial agent.[246] The applicant states that discontinuation of SOLIRIS may be associated with relapse and hospitalization. The second distinction made by the applicant is that the prescribing information for ENSPRYNG[247] does not bear a black-box warning, in contrast to that of SOLIRIS.[248] The third distinction is that patients must be vaccinated against *Neisseria meningitidis* before receiving SOLIRIS[249] and no such requirement applies to ENSPRYNG.[250] The fourth and final distinction made by the applicant highlights duration of treatment. In the SAkuraSky trial, the mean period of treatment in the double-blind period was 94.1±72.6 weeks in the ENSPRYNG group and 66.0±61.4 weeks in the placebo group.[251] However, the median trial durations were shorter in the SOLIRIS trial, at 90.93 and 43.14 weeks (minimum-maximum, 6.4–211.1 and 8.0–208.6) for the SOLIRIS and placebo groups, respectively.[252]

In connection with the applicant's fourth claim to support substantial clinical improvement, the applicant stated that both the SAkuraStar[253] and SAkuraSky[254] clinical trials included comparator arms. In SAkuraStar, an exclusion criterion was IST use, whereas in SAkuraSky, patients were permitted to continue baseline treatment with a stable dose of the IST agents in addition to the trial drug. This allowed the efficacy of ENSPRYNG to be assessed both in patients who were

[240] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[241] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[242] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[243] Greenberg B, Seze JD, Fox E. et al. Safety of satralizumab in neuromyelitis optica spectrum disorder (NMOSD): Results from the open-label extension periods of SAkuraSky and SAkuraStar Presentation at: Americas Committee for treatment and research in Multiple Sclerosis (ACTRIMS); September 2020; Virtual.

[244] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[245] Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(7)614–625. doi:10.1056/nejmoa1900866.

[246] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[247] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[248] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[249] SOLIRIS (eculizumab) [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 2019.

[250] ENSPRYNG (satralizumab) [prescribing information]. South San Francisco, CA: Genentech USA, Inc.; 2020.

[251] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[252] Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(7)614–625. doi:10.1056/nejmoa1900866.

[253] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[254] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019; 381(22)2114–2124. doi:10.1056/nejmoa1901747.

receiving one of the IST agents for their NMOSD and in the others who were receiving nothing at all. The applicant stated that in contrast, SOLIRIS was tested only in a single Phase 3 clinical trial where the primary end point was the first adjudicated relapse in the population of patients taking stable-dose IST and either SOLIRIS or placebo; the efficacy of SOLIRIS monotherapy was a sub analysis,[255] and UPLIZNA was tested only in a single Phase 3 clinical trial as a monotherapy with only a 28-week randomized, controlled period.[256] According to the applicant, ENSPRYNG has received approval by regulatory authorities in Japan,[257] Canada, and Switzerland [258] for the treatment of both adults and adolescents (12–17 years of age) with NMOSD. The applicant asserts that patients in the ENSPRYNG clinical trials likely are representative of Medicare patients despite their mean ages (45.3 years for the ENSPRYNG arm of SAkuraStar [259] and 40.8 years for the ENSPRYNG arm of SAkuraSky [260]) being less than 65, as NMOSD is so severe that patients may qualify for disability accompanied by Medicare benefits regardless of their age.[261] The applicant explained that a severe onset attack causing increased disability is reported to occur in 45% of patients with NMOSD [262] and that 52.4% of US-based NMOSD patients report severe problems with mobility,[263] which is consistent with definitions of disability used by the Social Security Administration (SSA).[264] Per the applicant, SSA maintains a list of impairments considered severe enough to prevent gainful activity. Though NMOSD is not listed, multiple sclerosis (MS) is,[265] and the two conditions are frequently confused due to similarities between clinical presentations.[266] According to the applicant, the SSA is open to allowing people to qualify for disability by showing their condition is as severe as one that is on the list.[267]

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for ENSPRYNG, we note that while the applicant provided data comparing ENSPRYNG to placebo with or without IST, the applicant did not provide data to demonstrate improved outcomes over existing FDA approved treatments for NMOSD. While the applicant states reasons why a comparison could not be made, additional information would help inform our assessment of whether ENSPRYNG demonstrates a significant clinical improvement over existing technologies for outcomes such as time to first relapse and annual relapse rate. In addition, while we understand that there may be potential benefits related to the self-administrative delivery of ENSPRYNG, we question if the benefits are related only to the outpatient administration of the medication and whether they would demonstrate improved clinical outcomes that represent a substantial clinical improvement in the inpatient setting. We are inviting public comments on whether ENSPRYNG meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ENSPRYNG.

h. ABECMA® (idecabtagene vicleucel)

Celgene Corporation, a wholly owned subsidiary of Bristol-Myers Squibb (BMS), submitted an application for new technology add-on payment for idecabtagene vicleucel for FY 2022. Idecabtagene viclecuel is a, B-cell maturation antigen (BCMA)-directed genetically modified autologous chimeric antigen receptor (CAR) T-cell immunotherapy for the treatment of adult patients with relapsed or refractory (RR) multiple myeloma (MM) (RRMM) who have received at least four prior therapies including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), and an anti-CD38 antibody (for example, triple-class-exposed). Idecabtagene vicleucel is expected to be a 5th line plus (5L+) treatment.

Multiple myeloma (MM) is typically characterized by the neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. The plasma cells proliferate in the bone marrow and can result in extensive skeletal destruction with osteolytic lesions, osteopenia, and/or pathologic fractures. The diagnosis of MM is often suspected because of one (or more) of the following clinical presentations:

- Bone pain with lytic lesions discovered on routine skeletal films or other imaging modalities
- An increased total serum protein concentration and/or the presence of a monoclonal protein in the urine or serum
- Systemic signs or symptoms suggestive of malignancy, such as unexplained anemia
- Hypercalcemia, which is either symptomatic or discovered incidentally
- Acute renal failure with a bland urinalysis or rarely nephrotic syndrome due to concurrent immunoglobulin light chain (AL) amyloidosis

It is important to distinguish MM both from other causes of these clinical presentations and from other plasma cell dyscrasias for the purposes of prognosis and treatment.[268] Data from the U.S. Surveillance, Epidemiology, and End Results (SEER) registry estimate 32,000 new cases of MM and

[255] Pittock SJ, Berthele A, Fujihara K, et al. Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(7)614–625. doi:10.1056/nejmoa1900866.

[256] Cree BAC, Bennett JL, Kim HJ, et al. Inebilizumab for the treatment of neuromyelitis optica spectrum disorder (N–MOmentum): a double-blind, randomised placebo-controlled phase 2/3 trial. Lancet 2019;394(10206)1352–1363. doi:10.1016/s0140–6736(19)31817–3.

[257] F. Hoffmann-La Roche Ltd. Roche's ENSPRYNG (satralizumab) Approved In Japan For Adults And Children With Neuromyelitis Optica Spectrum Disorder. *https://www.roche.com/media/releases/med-cor-2020-06-29.htm.* Accessed August 14, 2020.

[258] Heo Y. Satralizumab: First Approval. Drugs 2020;80(14)1477–1482. doi:10.1007/s40265–020–01380–2.

[259] Traboulsee A, Greenberg BM, Bennett JL, et al. Safety And Efficacy of Satralizumab Monotherapy In Neuromyelitis Optica Spectrum Disorder: A Randomised, Double-Blind, Multicentre, Placebo-Controlled Phase 3 Trial. Lancet Neurol. 2020;19(5):402–412. doi:10.1016/S1474–4422(20)30078–8.

[260] Yamamura T, Kleiter I, Fujihara K, et al. Trial of Satralizumab in Neuromyelitis Optica Spectrum Disorder. N. Engl. J. Med. 2019;381(22)2114–2124. doi:10.1056/nejmoa1901747.

[261] Social Security Administration. Medicare Information. *https://www.ssa.gov/disabilityresearch/wi/medicare.htm.* Accessed September 10, 2020.

[262] Kim S, Mealy MA, Levy M, et al. Racial differences in neuromyelitis optica spectrum disorder. Neurology 2018;91(22)e2089–e2099. doi:10.1212/wnl.0000000000006574.

[263] Mealy MA, Boscoe A, Caro J, et al. Assessment of Patients with Neuromyelitis Optica Spectrum Disorder Using the EQ–5D. Int. J. MS Care 2018; 21(3)129–134. doi:10.7224/1537–2073.2017–076.

[264] Social Security Administration. How You Qualify. *https://www.ssa.gov/benefits/disability/qualify.html.* Accessed October 2, 2020.

[265] Social Security Administration. Disability Evaluation Under Social Security. *https://www.ssa.gov/disability/professionals/bluebook/11.00-Neurological-Adult.htm#11_09.* Accessed September 10, 2020.

[266] Etemadifar M, Nasr Z, Khalili B, Taherioun M, Vosoughi R. Epidemiology of Neuromyelitis Optica In The World: A Systematic Review And Meta-Analysis. Mult Scler Int. 2015;2015:174720. doi:10.1155/2015/174720.

[267] Social Security Administration. How You Qualify. *https://www.ssa.gov/benefits/disability/qualify.html.* Accessed October 2, 2020.

[268] Laubauch, J.P. (2021). Multiple myeloma: Clinical features, laboratory manifestations, and diagnosis. UptoDate. Available from *https://www.uptodate.com/contents/multiple-myeloma-clinical-features-laboratory-manifestations-and-diagnosis?search=multiple%20myeloma&;source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.*

13,000 deaths from MM annually in the U.S. This correlates with an annual incidence of approximately 7 per 100,000 men and women per year. MM is largely a disease of older adults. The median age at diagnosis is 65 to 74 years. MM is also slightly more frequent in men than in women (approximately 1.4:1). MM is associated with substantial morbidity and mortality [269] and approximately 25% of patients have a median survival of 2 years or less.[270] With respect to the newness criterion, idecabtagene vicleucel received FDA approval on March 26, 2021, and has marketing authorization under the name of Abecma® and is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. A single dose of idecabtagene vicleucel contains a cell suspension of 300 to 460 × 106 CAR T-cells.

The applicant submitted a request for unique ICD–10–PCS codes that describe the administration of idecabtagene vicleducel at the September 2020 Coordination and Maintenance Committee meeting. The following codes were approved to describe procedures involving the administration of idecabtagene vicleucel: XW033L7 (Introduction of idecabtagene vicleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) and XW043L7 (Introduction of idecabtagene vicleucel immunotherapy into central vein, percutaneous approach, new technology group 7). These codes will be effective starting October 1, 2021.

As previously stated, if a technology meets all three of the substantial similarity criteria as previously described, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to whether a product uses the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, the applicant asserts that idecabtagene viceleucel does not use the same or similar mechanism of action as other therapies approved to treat 4L+ RRMM or CAR T-cell therapies approved to treat different diseases. According to the applicant, with regard to its mechanism of action, idecabtagene viceleucel is a chimeric antigen receptor (CAR)-positive T cell therapy targeting B-cell maturation antigen (BCMA), which is expressed on the surface of normal and malignant plasma cells. The CAR construct includes an anti-BCMA scFv-targeting domain for antigen specificity, a transmembrane domain, a CD3-zeta T cell activation domain, and a 4–1BB costimulatory domain. Antigen-specific activation of idecabtagene viceleucel results in CAR-positive T cell proliferation, cytokine secretion, and subsequent cytolytic killing of BCMA-expressing cells.

According to the applicant, with respect to the non-CAR T-cell therapies to treat 4L+ RRMM, specifically Xpovio®, Blenrep, and chemotherapy, idecabtagene vicleucel's mechanism of action is different because it is a CAR T-cell therapy. The applicant states that the mechanism of action for Xpovio® is reversible inhibition of nuclear export of tumor suppressor proteins (TSPs), growth regulators, and mRNAs of oncogenic proteins by blocking exportin 1 (XPO1). XPO1 inhibition by Xpovio® leads to accumulation of TSPs in the nucleus, reductions in several oncoproteins, such as c-myc (a ''master regulator'' which controls many aspects of cellular growth regulation and cellular metabolism) and cyclin D1, cell cycle arrest, and apoptosis of cancer cells. The applicant states that Blenrep's mechanism of action is cell destruction via microtubule inhibition, where the microtubule inhibitor is conjugated to a BCMA-specific antibody (antibody-drug conjugate). The applicant further states that the mechanism of action for chemotherapy regimens generally is disruption of normal processes required for cell survival, such as deoxyribonucleic acid (DNA) replication and protein synthesis or degradation.

With respect to the mechanism of action of other currently FDA approved CAR T-cell therapies, according to the applicant, there are no other FDA approved CAR T-cell therapies that are indicated for treatment of RRMM with the same or similar mechanism of action as idecabtagene vicleucel. The applicant stated that CAR T-cell therapies employ a unique mechanism of action which modifies the patient's own T-cell to express a chimeric antigen receptor (CAR) that programs T-cells to destroy cells that express a specific target. In the case of idecabtagene vicleucel, this target is BCMA, which is a protein that is highly expressed on the surface of MM cells making it an ideal target for the treatment of MM. The applicant asserts that the key feature that distinguishes idecabtagene vicleucel from CD–19 directed CAR T-cell therapies is the BCMA targeting domain. According to the applicant, idecabtagene vicleucel's BCMA targeting domain means that idecabtagene vicleucel has a completely different mechanism of action from other currently FDA approved CAR T-cell therapies. In its application, the applicant asserted that since there are currently no FDA approved anti-BCMA CAR T-cell therapies, if approved, idecabtagene vicleucel is the first CAR T-cell therapy approved for the treatment of RRMM and the only approved CAR T-cell therapy with a BCMA targeting domain which makes it unique as compared to other currently approved FDA therapies used to treat RRMM.

With regard to whether a product is assigned to the same DRG when compared to an existing technology, the applicant stated that it expects that cases involving the administration idecabtagene vicleucel will be assigned to the same MS–DRG, MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), as other CAR T-cell therapies.

With regard to whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant asserted that, if FDA approved, idecabtagene vicleucel will be the first and only anti-BCMA CAR T-cell therapy available to treat RRMM. The applicant further asserted that idecabtagene vicleucel would be indicated for a broader population than other currently FDA-approved available therapies, specifically multiple myeloma patients having received four prior therapies.

In summary, according to the applicant, because idecabtagene vicleucel has a unique mechanism of action when compared to other currently FDA approved treatments for RRMM, and does not involve the treatment of the same or similar type of disease (RRMM) or the same or similar patient population (triple-class-exposed adult patients with RRMM), the technology is not substantially similar to an existing technology and therefore meets the newness criterion. However, we question whether idecabtagnene vicleucel's mechanism of action may be similar to that of ciltacabtagene autoleucel, another CAR T-cell therapy for which an application for new technology add-on payments was

[269] R?owan AJ, Allen C, Barac A, et al. Global Burden of Multiple Myeloma: A Systematic Analysis for the Global Burden of Disease Study 2016. JAMA Oncol. 2018;4(9):1221–1227. doi:10.1001/jamaoncol.2018.2128.

[270] Biran, N., Jagannath, S., Risk Stratification in Multiple Myeloma, Part 1: Characterization of High-Risk Disease 2013. Clinical Adv in Hematology & Oncology 11(8); 489–503.

submitted for FY 2022 as discussed previously. Both idecabtagene vicleucel and ciltacabtagene autoleucel seem to be intended for similar patient populations; multiple myeloma patients with three or more prior therapies, and would involve the treatment of the same conditions; adult patients with relapsed or refractory multiple myeloma. We are interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether idecabtagene vicleucel and ciltacabtagne autoleucel, if approved by July 1, 2021, are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comments on whether idecabtagene vicleucel is substantially similar to an existing technology and whether it meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR correction notice (December 1, 2020) file to identify potential cases representing patients who may be eligible for treatment using idecabtagene vicleucel. In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The following ICD–10–CM diagnosis codes were used to identify claims involving multiple myeloma procedures.

ICD-10-CM Code	Code Description
C90.00	Multiple myeloma not having achieved remission
C90.02	Multiple myeloma in relapse

The applicant chose to limit its analysis to MS–DRG 016 (Autologous Bone Marrow Transplant W CC/MCC or T-Cell Immunotherapy, MS–DRG 840 (Lymphoma & Non-Acute Leukemia W MCC) and MS–DRG 841 (Lymphoma & Non-Acute Leukemia W CC). The claim search conducted by the applicant resulted in 1,955 claims mapped to MS–DRG 016, MS–DRG 840 and MS–DRG 841 using the FY 2019 MedPAR. The applicant determined an average unstandardized case weighted charge per case of $1,237,393. The applicant used the MS–DRG–018 New Technology Threshold for FY 2022 from the FY 2021 IPPS/LTCH PPS final rule.

The applicant removed all charges in the drug cost center for the prior technology because, according to the applicant, it is not possible to differentiate between different drugs on inpatient claims. The applicant added that this is likely an overestimate of the charges that would be replaced by the use of idecabtagene vicleucel. The applicant then standardized the charges using the FY 2019 final rule impact file. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used a national average CCR for the CAR T-cell therapies of 0.295. To determine this alternative CCR for CAR T-cell therapies, the applicant referred to the FY 2021 IPPS/LTCH PPS final rule AOR/BOR file and calculated an alternative markup percentage by dividing the AOR drug charges within DRG 018 by the number of cases to determine a per case drug charge. The applicant then divided the drug charges per case by $373,000, the acquisition cost of YESCARTA and KYMRIAH. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,329,540, which exceeded the average case-weighted threshold amount of $1,251,127 by $78,413. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR, we are uncertain how representative this data is for use in the applicant's cost analyses given the potential for variability.

We continue to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

We invite public comment on whether idecabtagene vicleucel meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that it believes that idecabtagene vicelucel represents a substantial clinical improvement over existing technologies because: (1) The totality of the circumstances regarding idecabtagene vicleucel's clinical efficacy, safety, and data make clear that idecabtagene vicleucel substantially improves, relative to services or technologies currently available, the treatment of Medicare beneficiaries with RRMM; (2) idecabtagene vicleucel has superior effectiveness compared to existing therapies; (3) idecabtagene vicleucel fills an unmet need as demonstrated by the patient population in its registrational study, which is reflective of real-world RRMM patients and (4) idecabtagene vicleucel improves quality of life for patients with RRMM.

In support of its assertion that the totality of the circumstances regarding idecabtagene vicleucel's clinical efficacy, safety, and data make clear that idecabtagene vicleucel substantially improves, relative to services or technologies currently available, the treatment of Medicare beneficiaries with RRMM, the applicant cited results from the KarMMA study, a single-arm, open-label, phase 2 trial of idecabtagene vicleucel. The primary outcome measure for the KarMMA study was overall response rate (ORR). Secondary endpoints were; complete response rate (CRR) (key secondary; null hypothesis ≤10%), safety, duration of response (DOR), progression-free survival (PFS), overall survival (OS), pharmacokinetics (PK), minimum residual disease (MRD), quality of life (QOL) and health economics and outcomes research (HEOR). The study enrolled 140 patients and 128 received treatment. Patients were treated at target dose between 150 and 450 x 10^6 CAR T-cells. Treated patients had received three or more prior lines of therapy including an immunomodulatory drug (IMiD), a proteasome inhibitor (PI), and an anti-CD38 antibody. All patients were refractory to the last regimen (94% were refractory to anti-CD38 and 84% were

refractory to triple therapy). Efficacy results showed an ORR of 50% for patients (n=4) receiving the target idecabtagene vicleucel dose of 150 x10^6; 68.6% for patients (n=70) receiving the target dose of 300 x10^6; 81.5% for patients (n=54) receiving the target dose of 450 x 10^6. The overall ORR for all patients (n=128) who received idecabtagene vicleucel was 73.4%.

The applicant asserts that in the KarMMA study, patients who received idecabtagene vicleucel achieved numerically superior response rates, duration of response, and overall survival compared with outcomes seen for alternative therapies (belantamab-mafodotin and selinexor) in other trials.[271] [272] [273] [274] [275] [276] Response rates, according to the applicant, were also high even in patients refractory to five therapies (defined as 2 IMiD agents, 2 PIs, and 1 anti-CD38 antibody), reflecting the novel mechanism of action, according to the applicant. The applicant asserts that compared with anti-CD–19 CAR T-cell therapies, the adverse event profile revealed low rates of grade 3+ CRS (5%) and neurotoxicity (NT) (3%).[277] According to the applicant, these safety results confirm that idecabtagene vicleucel has the potential to offer a meaningful benefit to Medicare beneficiaries. The applicant also asserts that idecabtagene vicluecel has been demonstrated to be effective and with a manageable safety profile for patients with a high-unmet need (older age, aggressive disease). The applicant asserts that the results from the pivotal KarMMa study confirm the clinical benefit of idecabtagene vicleucel in a heavily pre-treated RRMM patient population.

We note that in contrast with anti-CD–19 CAR T-cell therapies (for leukemia or lymphoma) where a high fraction of responders remained in remission even after 5 years, idecabtagene vicleucel does not appear to result in long-term remission. In the KarMMA study, among responding patients, over 75% relapsed by 20 months, with no plateauing of the response curve.[278]

To support its assertion that idecabtagene vicleucel has superior effectiveness compared to existing therapies, the applicant provided results from the KarMMa–RW study,[279] a single-arm, open-label, phase 2 trial, examining real-world treatment patterns in heavily pretreated patients with RRMM. The study also provides a comparison against outcomes in the KarMMa study. The KarMMa–RW study was conducted to assess treatment patterns in real-world RRMM patients with characteristics similar to the KarMMa population and to compare outcomes with currently available therapies in this synthetic cohort vs idecabtagene vicleucel therapy in the KarMMa study. The primary endpoint of the KarMMA–RW study was overall response rate (ORR). Secondary endpoints of the study were complete response rate (CRR), very good partial response (VGPR) rate, progression free survival (PFS) and overall survival (OS). Subgroup analyses by age, sex, double-class refractory (IMiD agents and PIs) and number of prior anti-myeloma regimens per year (≤1 per year or >1) were conducted to compare ORR and PFS between the KarMMa cohort and eligible RRMM cohort. Since complete response assessment requires a bone marrow biopsy evaluation, per International Myeloma Working Group (IMWG) uniform response criteria for multiple myeloma, when data to assess a complete response were not available in eligible RRMM cohort, analyses were summarized for VGPR or better (≥VGPR) to avoid underestimating the response in the eligible RRMM cohort.

Of 1,949 real-world RRMM patients, 1,171 were refractory to their last treatment regimen at baseline. Patients who had exposure to any BCMA-directed therapy or gene-modified therapy were excluded. Of the 1,171 patients in the refractory RRMM cohort, 528 received the next line of therapy; 643 patients were excluded due to no new treatment due to death (n = 441) and no new treatment due to no follow-up (n = 202). Of the remaining 528 patients, 190 triple class exposed patients were selected as the eligible RRMM cohort based on the KarMMa eligibility criteria. The ORR in the KarMMa and eligible RRMM cohorts was 76% and 32% (p= <0.0001), respectively. The VGPR in the KarMMa and eligible RRMM cohorts was 57% and 14% (p= <0.0001), respectively.

A matched-paired analysis was conducted and ORR was adjusted for matching. Results from the matched-paired analysis were consistent with the primary analysis: the ORR for the matched KarMMa cohort (n = 76–80) and matched eligible RRMM (n = 76–80) was 72% and 29% (p=<0.0001), respectively. According to the applicant, PFS was significantly improved in KarMMa vs the eligible RRMM cohort; median PFS was 11.3 months and 3.5 months in the KarMMa and Eligible RRMM cohorts, respectively (p= <0.0001). Median follow-up was 11.3 months (KarMMa) and 10.2 months (eligible RRMM cohort) at data cutoff. According to the applicant, OS was significantly improved in KarMMa vs the eligible RRMM cohort. OR was 18.2 months for the KarMMa cohort (across all target doses from 150–450 $\times 10^6$ CAR T-cells) and 14.7 months for the eligible RRMM cohort. The estimated 12-month probability of surviving was 80% in the KarMMa cohort and 56% in the eligible RRMM cohort. Median follow-up was 12.0 months (KarMMa) and 15.0 months (eligible RRMM cohort) among surviving patients at data cutoff.

The applicant asserts that the results from the KarMMa–RW study confirm that there is no clear standard of care for RRMM patients who received at least 3 prior therapies, including IMiD agents, PIs, and anti-CD38 antibodies. Patients in the eligible RRMM cohort received 94 different treatment regimens as next-line therapy and according to the applicant, outcomes were sub-optimal with currently available therapies in the real-world RRMM patients. The applicant asserts that significantly improved outcomes were demonstrated with idecabtagene vicleucel treatment in the KarMMa cohort vs the similar real-

[271] Munshi NC, Anderson, Jr LD, Shah N, et al. Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial KarMMa results. J Clin Oncol. 2020;38(15_suppl):8503–8503. doi:10.1200/JCO.2020.38.15_suppl.8503.

[272] Rodriguez-Otero P, Weisel K, Davies F, et al. Matching-adjusted indirect comparisons of efficacy outcomes for idecabtagene vicleucel from the KARMMA study vs selinexor plus dexamethasone (STORM part 2) and belantamab mafodotin (DREAMM–2). In: European Hematology Association.; 2020.

[273] Jagannath S, Lin Y, Goldschmidt H, et al. KarMMa-RW: A study of real-world treatment patterns in heavily pretreated patients with relapsed and refractory multiple myeloma (RRMM) and comparison of outcomes to KarMMa. J Clin Oncol. 2020;38(15_suppl):8525–8525. doi:10.1200/jco.2020.38.15_suppl.8525.

[274] Raje N, Berdeja J, Lin Y, et al. Anti-BCMA CAR T-cell therapy bb2121 in relapsed or refractory multiple myeloma. N Engl J Med. 2019;380(18):1726–1737. doi:10.1056/NEJMoa1817226.

[275] Lonial S, Lee HC, Badros A, et al. Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM–2): a two-arm, randomised, open-label, phase 2 study. Lancet Oncol. 2020;21(2):207–221. doi:10.1016/S1470–2045(19)30788–0.

[276] Chari A, Vogl DT, Gavriatopoulou M, et al. Oral Selinexor–Dexamethasone for Triple-Class Refractory Multiple Myeloma. N Engl J Med. 2019;381(8):727–738. doi:10.1056/nejmoa1903455.

[277] Munshi NC, Anderson, Jr LD, Shah N, et al. Idecabtagene vicleucel (ide-cel; bb2121), a BCMA-targeted CAR T-cell therapy, in patients with relapsed and refractory multiple myeloma (RRMM): Initial KarMMa results. *J Clin Oncol.* 2020;38(15_suppl):8503–8503.

[278] Ibid.

[279] Jagannath S, Lin Y, Goldschmidt H, et al. KarMMa–RW: A study of real-world treatment patterns in heavily pretreated patients with relapsed and refractory multiple myeloma (RRMM) and comparison of outcomes to KarMMa. *J Clin Oncol.* 2020;38(15_suppl):8525–8525.

world population (eligible RRMM cohort). The applicant noted that the real world myeloma patient population is older (MM incidence is known to increase with age, with over 60 percent of all new cases occurring in adults aged 65+years).[280] The applicant asserts that results were consistent across subgroups including patients aged ≥65 years.

The applicant also provided a comparison of the efficacy of idecabtagene and Xpovio® from the STORM study and Blenrep from the DREAMM–2 study. STORM is a prospective, multicenter phase 2 study of Xpovio® and dexamethasone in patients with RRMM (n=122) in the 4L+ setting. The STORM trial served as the basis for regulatory approval in the US and demonstrated the clinical efficacy and safety of Xpovio®. The ORR was 26% for patients in the STORM study vs 73% for patients treated with idecabtagene vicleucel in the KarMMa study, CR was 1% for patients in the STORM study vs 33% for patients treated with idecabtagene vicleucel in the KarMMa study, medium duration of response (mDOR) was 4.4 months for patients in the STORM study vs 10.7 months for patients treated with idecabtagene vicleucel in the KarMMa study, and PFS was 3.7 months for patients in the STORM study vs 8.8 months for patients treated with idecabtagene vicleucel in the KarMMa study. The DREAMM–2 study is a prospective, multicenter Phase 2 study of Blenrep in patients with RRMM (n=122) in the 4L+ setting. The ORR was 31% for patients in the DREAMM–2 study vs 73% for patients treated with idecabtagene vicleucel in the KarMMa study, CR was 3% for patients in the DREAMM–2 study vs 33% for patients treated with idecabtagene vicleucel in the KarMMa study, medium duration of response (mDOR) was not reached in the Blenrep group whereas it was 10.7 months for patients treated with idecabtagene vicleucel in the KarMMa study, and PFS was 2.9 months for patients in the DREAMM–2 study vs 8.8 months for patients treated with idecabtagene vicleucel in the KarMMa study.

Because idecabtagne vicleucel showed improved ORR, CR, medDOR and PFS when compared to Xpovio® and Blenrep, the applicant asserts that idecabtagne vicleucel provides a substantial clinical improvement over these existing therapies.

To support that idecabtagene vicleucel fills an unmet need as demonstrated by the patient population in its registrational study, the Phase 2 KarMMa study, the applicant asserts that in addition to showing deep and durable responses and a manageable safety profile in heavily pretreated, highly refractory RRMM patients in the context of controlled clinical studies, comparisons of outcomes in real world patients (that is, patients not enrolled in clinical trials) support the assertion that idecabtagene vicleucel offers significantly improved outcomes for RRMM compared with currently available therapies. The applicant asserts that when compared to myeloma patients generally included in clinical studies, the real world myeloma patient population is older (MM incidence is known to increase with age, with over 60 percent of all new cases occurring in adults aged ≥65 years) [281] and sicker (due to the high proportion of elderly patients in this population, those with MM commonly also have additional comorbidities associated with increased age, including conditions such as osteoporosis, arthritis, diabetes, additional malignancies, cardiovascular disease, and renal dysfunction, amongst others).[282] The applicant provided an abstract from the MAMMOTH study, a noninterventional, retrospective cohort analysis conducted to assess outcomes in patients after they become refractory to anti-CD38 monoclonal antibodies, including a subset of patients who were triple-class-exposed. Patients in STORM (analyzing Xpovio® plus dexamethasone) had an ORR of 32.8% versus 25% for patients receiving conventional care in MAMMOTH (p=0.078) and STORM patients had better OS than patients in MAMMOTH (median 10.4 vs 6.9 months) (p=0.043). The applicant asserts that these results highlight a high unmet need in a patient population refractory to anti-CD38 monoclonal antibody, including a subset of triple-class exposed patients.

To support the assertion that idecabtagene vicleucel improves quality of life for patients with RRMM, the applicant referenced idecabtagene vicleucel's impact on Health-related quality of life (HRQoL) as assessed in the KarMMa study as a secondary endpoint. HRQoL was assessed using the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life C30 Questionnaire (QLQ–C30) and the EORTC Multiple Myeloma Module (MY20). The QLQ–C30 consists of 30 questions addressing 5 functional domain scales, 3 symptom scales, a Global ealth/QoL scale, and 6 single item measures.[283] The QLQ–MY20 consists of 20 questions addressing 4 myeloma-specific HRQoL domains (disease symptoms, side effects of treatment, future perspectives, and body image).[283] Primary subscales of interest were QLQ–C30 Fatigue, Pain, Physical Functioning, Cognitive Functioning, and Global Health/QoL subscales and QLQ–MY20 Symptom and Side Effects subscales. Subscales were preselected based on their relevance to this patient population. The data are based on a minimum of 10 months post-infusion. Median follow-up durations at the target dose levels of 150, 300, and 450×10^6 CAR T-cells were 17.8, 13.9, and 9.7 months, respectively. Of 140 patients enrolled in KarMMa, 128 received idecabtagene vicleucel, of whom 121 (94.5%) and 120 (93.8%) were evaluable for HRQoL by QLQ–C30 and QLQ–MY20, respectively. At baseline, idecabtagene vicleucel treated patients had less favorable scores for all QLQ–C30 domains of interest (fatigue, pain, Global Health/QoL, physical functioning and cognitive functioning) than the general population. From baseline at multiple time points through month 9 post-infusion, the applicant asserts that clinically meaningful improvements were observed in QLQ–C30 Fatigue, Pain, Physical Functioning, and Global Health subscale scores relative to baseline, as the mean score from baseline showed improvement in all domains. The applicant asserts that these results support that idecabtagene vicleucel provides meaningful improvements in HRQoL and self-reported symptoms associated with heavily pretreated RRMM and demonstrate that idecabtagene vicleucel provides meaningful improvement in both global function and symptoms related to MM.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for idecabtagene vicleucel, we question whether, due to the lack of randomization, there is sufficient evidence to establish the efficacy of idecabtagene vicleucel compared with current alternatives. It is unknown whether the superior

[280] Cancer Stat Facts: Myeloma, NCI SEER, *https://seer.cancer.gov/statfacts/html/mulmy.html* (last visited October. 7, 2020).

[281] Cancer Stat Facts: Myeloma, NCI SEER, *https://seer.cancer.gov/statfacts/html/mulmy.html* (last visited Oct. 7, 2020).

[282] Hari P et al. The impact of age and comorbidities on practice patterns and outcomes in patients with relapsed/refractory multiple myeloma in the era of novel therapies. Journal of Geriatric Oncology. 2018;9(2):138–144 (Hari, 2018).

[283] Helena Maes & Michel Delforge (2015) Optimizing quality of life in multiple myeloma patients: current options, challenges and recommendations, Expert Review of Hematology, 8:3, 355–366, DOI: 10.1586/17474086.2015.1021772.

outcomes for idecabtagene vicleucel in the KarMMA study, which has not been peer-reviewed, were due to more effective therapy or other factors, such as differences in patient population or treating oncologist. We also note that the applicant chose to use ORR data as a measure of substantial clinical improvement rather than the more clinically relevant and available OS data.

We are inviting public comment on whether idecabtagene vicleucel meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Techology Add-on Payment Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for idecabtagene vicleucel.

i. INDIGO Aspiration System With Lightning Aspiration Tubing

Penumbra, Inc. submitted an application for the INDIGO® Aspiration System with Lightning Tubing (''INDIGO® with Lightning'') for FY 2022. Per the applicant, INDIGO® with Lightning is a mechanical thrombectomy aspiration system used in the treatment of pulmonary embolism, deep vein thrombosis and peripheral arterial thromboembolism that optimizes thrombus removal by differentiating between thrombus and blood.

According to the applicant, INDIGO® with Lightning performs clot detection and removal via smart technology which enables the physician to determine when the catheter is in thrombus and when it is in patent flow resulting in blood loss reduction through intermittent aspiration mechanical thrombectomy. The applicant stated that INDIGO® with Lightning is used for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems, and for the treatment of pulmonary embolism. The applicant stated that the INDIGO® with Lightning is composed of a mechanical thrombectomy aspiration pump (known as the Penumbra Engine) that is packaged with INDIGO® CAT12 (12 French) and CAT8 (8 French) catheters as well as Lightning, a clot detection/blood loss reduction technology embedded in the Penumbra Engine pump and tubing.

Arterial thromboembolism can result in acute limb ischemia (ALI) which requires emergent treatment. Venous thromboembolism is a condition which includes both deep vein thrombosis (DVT) and pulmonary embolism (PE) and occurs in 1 to 2 individuals per 1000 per year and is predominantly a disease of older age.[284] The 2020 American Society of Hematology guidelines for venous thromboembolism include recommendations for the treatment of patients with both pulmonary embolism and deep vein thrombosis, and recommended treatments include home care, systemic pharmacological thrombolysis, and procedural care.[285]

Procedural care may include open procedures as well as catheter-directed thrombolysis and percutaneous mechanical thrombectomy.[286] In catheter-directed thrombolysis, a thrombolytic agent is infused intravascularly adjacent to the clot burden through a percutaneous transcatheter.[287] In percutaneous mechanical thrombectomy, the thrombus is lysed or removed mechanically. The therapies may be used separately or in conjunction with one another.[288]

The applicant stated that mechanical thrombectomy may be performed with a variety of devices. These methods include aspiration thrombectomy, rheolytic thrombectomy, and fragmentation thrombectomy.[289]

The applicant stated that INDIGO® with Lightning differs from other mechanical thrombectomy devices on the basis of the use of a mechanical pump to generate a vacuum for aspiration and ''intelligent aspiration'' which differentiates clots and patient blood flow, thereby limiting blood loss. The applicant states that other endovascular mechanical thrombectomy devices do not provide aspiration using a vacuum. According to the applicant, the Lightning tubing performs clot detection using a proprietary algorithm. According to the applicant, once this ''smart technology'' detects free-flowing blood, it indicates patent flow to the physician and begins intermittent aspiration resulting in less blood loss during the procedure.

The applicant indicated that there is no unique ICD–10–PCS procedure code to describe the use of INDIGO® with Lightning. The applicant submitted a request for a unique ICD–10–PCS code to identify the technology beginning FY 2022.

INDIGO® with Lightning is a system with multiple components which have been reviewed by FDA both separately and as part of an overall system which includes catheters, tubing, and a vacuum pump. For the catheter portion of the system, INDIGO® aspiration catheter 12 (12 French) and separator 12 received FDA 510(k) clearance on May 28, 2020 for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems under FDA submission number K192981. The applicant states that they submitted an application for FDA 510(k) clearance for that same technology (with a predicate which received clearance mentioned previously under submission number K192981) for indication of pulmonary embolism under FDA submission number K202821 for which clearance was completed on November 18, 2020. The INDIGO® aspiration catheter 12 and separator 12 received FDA 510(k) clearance for the peripheral arterial and venous system on the basis of similarity to an earlier version of the same catheter and separator, which itself received FDA 510(k) clearance on May 26, 2015 under FDA 510(k) number K142870 as part of the Penumbra Embolectomy System for the same indication. We note that the overall system received a second 510(k) clearance on December 20, 2019 under FDA 510(k) number K192833 for the added indication of PE.

With respect to the newness criterion for the tubing, the Lightning tubing received FDA 510(k) authorization for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems on March 13, 2020 under FDA 510(k) number K193244. The same tubing received FDA 510(k) authorization for pulmonary embolism on April 22, 2020 under FDA

[284] Heit, John A. ''Epidemiology of venous thromboembolism.'' *Nature reviews. Cardiology* vol. 12,8 (2015): 464–74. doi:10.1038/nrcardio.2015.83

[285] Thomas L. Ortel, Ignacio Neumann, Walter Ageno, Rebecca Beyth, Nathan P. Clark, Adam Cuker, Barbara A. Hutten, Michael R. Jaff, Veena Manja, Sam Schulman, Caitlin Thurston, Suresh Vedantham, Peter Verhamme, Daniel M. Witt, Ivan D. Florez, Ariel Izcovich, Robby Nieuwlaat, Stephanie Ross, Holger J. Schünemann, Wojtek Wiercioch, Yuan Zhang, Yuqing Zhang; American Society of Hematology 2020 guidelines for management of venous thromboembolism: treatment of deep vein thrombosis and pulmonary embolism. *Blood Adv* 2020; 4 (19): 4693–4738. doi: *https://doi.org/10.1182/bloodadvances.2020001830.*

[286] Karthikesalingam A, Young EL, Hinchliffe RJ, Loftus IM, Thompson MM, Holt PJ. A systematic review of percutaneous mechanical thrombectomy in the treatment of deep venous thrombosis. *Eur J Vasc Endovasc Surg.* 2011 Apr;41(4):554–65. doi: 10.1016/j.ejvs.2011.01.010. Epub 2011 Feb 1. PMID: 21288745.

[287] Brown KN, Devarapally SR, Lee L, et al. Catheter Directed Thrombolysis Of Pulmonary Embolism. [Updated 2020 Apr 10]. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan. *https://www.ncbi.nlm.nih.gov/books/NBK536918/.*

[288] Karthikesalingam A, Young EL, Hinchliffe RJ, Loftus IM, Thompson MM, Holt PJ. A systematic review of percutaneous mechanical thrombectomy in the treatment of deep venous thrombosis. *Eur J Vasc Endovasc Surg.* 2011 Apr;41(4):554–65. doi: 10.1016/j.ejvs.2011.01.010. Epub 2011 Feb 1. PMID: 21288745.

[289] Haude, M. Mechanical thrombectomy catheter systems. *Interventional Cardiology* 2007;2(1):58–60.

510(k) number K200771, which was granted based on substantial similarity to the same manufacturer's device. The predicate device for the peripheral arterial and venous system was an earlier version of the tubing without Lighting which itself received FDA 510(k) authorization on May 3, 2018 under FDA 510(k) number K180939.

With respect to the newness criterion for the vacuum pump, the Penumbra Engine Pump and Canister received FDA 510(k) clearance for use in the peripheral arterial and venous systems (PAVS) on March 8, 2018 under FDA 510(k) number K180105. The following table summarizes the FDA approval information listed in this section.

INDIGO® System	Indication	Reference Number	Date of Clearance
INDIGO® - Penumbra Embolectomy Aspiration System	PAVS	K142870	May 26, 2015
INDIGO® - Advanced 110 Aspiration Tubing	PAVS	K180939	May 3, 2018
INDIGO® - INDIGO Aspiration System	PE	K192833	December 20, 2019
INDIGO® - Penumbra ENGINE Pump and Canister	PAVS	K180105	March 8, 2018
INDIGO® - LIGHTNING Aspiration Tubing	PAVS	K193244	March 13, 2020
INDIGO® - LIGHTNING Aspiration Tubing	PE	K200771	April 22, 2020
INDIGO® – Aspiration Catheter 12 and Separator 12	PAVS	K192981	May 28, 2020
INDIGO® – Aspiration Catheter 12 and Separator 12	PE	K202821	November 18, 2020

The applicant has applied for new technology add-on payments for INDIGO® with Lightning when used for the treatment of venous thromboembolism, arterial thromboembolism, and pulmonary thromboembolism.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that INDIGO® with Lightning does not use the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome. The applicant described differences between INDIGO® with Lightning and existing technologies based on the use of a mechanical pump to generate a vacuum for aspiration and the Lightning tubing, which the applicant stated limits blood loss and indicates clot versus patent flow. For pulmonary embolism and the peripheral system, the applicant identified Inari Flowtriever as an existing technology and noted that any aspiration provided using this system is provided via syringe as opposed to a vacuum pump. For the peripheral system, the applicant also identified Inari Flowtriever as using the same syringe method of aspiration. The applicant also identified two additional aspiration thrombectomy catheters, Angiojet® and Angiovac®, used in the peripheral system and suggested that Angiojet® also uses a syringe for aspiration and that Angiovac® utilizes an extracorporeal bypass circuit that is created outside the body consisting of an outflow line, a centrifugal pump, a filter and an inflow line.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that services provided using this device would be captured under MS–DRGs 163–165 and 270–272. MS–DRGs 163–165 address major chest procedures and MS–DRGs 270–272 address other major cardiovascular procedures.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant did not address this criterion directly in the application, but stated that the new use of the INDIGO® System with Lighting is for the most recent FDA indication (April 2020) in PE. The applicant further states that PE is not the same disease as arterial and venous thromboembolism; the patient populations may overlap, but are not identical.

We have the following concerns regarding whether the technology meets the substantial similarity criteria and whether it should be considered new. While the applicant discussed the differences between INDIGO® with Lighting and products made by other manufacturers, the applicant does not provide enough information regarding how INDIGO® with Lightning differs in its components from the existing aspiration thrombectomy catheters on the market to determine whether the technology uses a unique mechanism of action. We question whether the mechanism of action of the pump is different than that of the existing aspiration thrombectomy systems that also use a pump rather than a syringe, and how the mechanism of action of the separator, which is part of the catheter portion of the device, is different from that of existing thrombectomy systems that deploy a device through the lumen of the catheter to break up the thrombus. It is also unclear what mechanism of action is used within the ''smart technology'' and how it may differ from other products which are intended to similarly reduce blood loss during the procedure. It is unclear if the ''smart technology'' resides within the pump, which was cleared by FDA 510(k) on March 8, 2018, or within the tubing, which was most recently cleared by FDA 510(k) on April 22, 2020. We note that while the applicant did not directly address the third criterion within the application, based on the clinical uses of the device described in the application, we believe the INDIGO® with Lightning is intended for a patient population that is similar to the patient population treated by existing thrombectomy devices, including patients who receive percutaneous interventions for PE and peripheral arterial thromboembolism.

We note that the predicate device for the vacuum pump, the Penumbra Engine Pump and Canister, received FDA 510(k) clearance for use in the peripheral arterial and venous systems on March 8, 2018 under FDA 510(k) number K180105 and therefore appears to no longer be considered new. We further note that the catheter and tubing, as described in the 510(k) applications, appear to only have minor differences from their predicate devices such as length of tubing and shelf life, as opposed to elements that would affect the mechanism of action. If we determine that the catheter and tubing are substantially similar to the predicate

devices cleared under FDA 510(k) numbers K142870 (May 26, 2015) and K180939 (May 3, 2018), respectively, the newness date of the INDIGO® with Lightning would correspond to the dates listed and therefore may no longer be considered new. We also note that it is unclear whether the components of the system may be substantially similar to the overall system and whether the applicable newness date for each indication would therefore be the date of the overall system clearance for each indication, specifically May 26, 2015 for peripheral arterial and venous systems and December 20, 2019 for pulmonary embolism.

We invite public comment on whether INDIGO® with Lightning is substantially similar to other technologies and whether INDIGO® with Lightning meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file with the FY 2019 Final Rule with Correction Notice IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using the INDIGO® System. The applicant identified claims with any one of the following ICD–10–PCS codes for percutaneous mechanical thrombectomy:

Pulmonary Embolism	
02CP3ZZ	Extirpation of matter from pulmonary trunk, percutaneous approach
02CQ3ZZ	Extirpation of matter from right pulmonary artery, percutaneous approach
02CR3ZZ	Extirpation of matter from left pulmonary artery, percutaneous approach
02CS3ZZ	Extirpation of matter from right pulmonary vein, percutaneous approach
02CT3ZZ	Extirpation of matter from left pulmonary vein, percutaneous approach
Deep Vein Thrombosis/Vascular	
04CC3Z6	Extirpation of matter from right common iliac artery, bifurcation, percutaneous approach
04CC3ZZ	Extirpation of matter from right common iliac artery, percutaneous approach
04CD3Z6	Extirpation of matter from left common iliac artery, bifurcation, percutaneous approach
04CD3ZZ	Extirpation of matter from left common iliac artery, percutaneous approach
04CE3Z6	Extirpation of matter from right internal iliac artery, bifurcation, percutaneous approach
04CE3ZZ	Extirpation of matter from right internal iliac artery, percutaneous approach
04CF3Z6	Extirpation of matter from left internal iliac artery, bifurcation, percutaneous approach
04CF3ZZ	Extirpation of matter from left internal iliac artery, percutaneous approach
04CH3Z6	Extirpation of matter from right external iliac artery, bifurcation, percutaneous approach
04CH3ZZ	Extirpation of matter from right external iliac artery, percutaneous approach
04CJ3Z6	Extirpation of matter from left external iliac artery, bifurcation, percutaneous approach
04CJ3ZZ	Extirpation of matter from left external iliac artery, percutaneous approach
04CK3Z6	Extirpation of matter from right femoral artery, bifurcation, percutaneous approach
04CK3ZZ	Extirpation of matter from right femoral artery, percutaneous approach
04CL3Z6	Extirpation of matter from left femoral artery, bifurcation, percutaneous approach
04CL3ZZ	Extirpation of matter from left femoral artery, percutaneous approach
04CM3Z6	Extirpation of matter from right popliteal artery, bifurcation, percutaneous approach
04CM3ZZ	Extirpation of matter from right popliteal artery, percutaneous approach
04CN3Z6	Extirpation of matter from left popliteal artery, bifurcation, percutaneous approach
04CN3ZZ	Extirpation of matter from left popliteal artery, percutaneous approach
04CP3Z6	Extirpation of matter from right anterior tibial artery, bifurcation, percutaneous approach
04CP3ZZ	Extirpation of matter from right anterior tibial artery, percutaneous approach
04CQ3Z6	Extirpation of matter from left anterior tibial artery, bifurcation, percutaneous approach
04CQ3ZZ	Extirpation of matter from left anterior tibial artery, percutaneous approach
04CR3Z6	Extirpation of matter from right posterior tibial artery, bifurcation, percutaneous approach
04CR3ZZ	Extirpation of matter from right posterior tibial artery, percutaneous approach
04CS3Z6	Extirpation of matter from left posterior tibial artery, bifurcation, percutaneous approach
04CS3ZZ	Extirpation of matter from left posterior tibial artery, percutaneous approach
04CT3Z6	Extirpation of matter from right peroneal artery, bifurcation, percutaneous approach
04CT3ZZ	Extirpation of matter from right peroneal artery, percutaneous approach
04CU3Z6	Extirpation of matter from left peroneal artery, bifurcation, percutaneous approach
04CU3ZZ	Extirpation of matter from left peroneal artery, percutaneous approach
06CC3ZZ	Extirpation of matter from right common iliac vein, percutaneous approach
06CD3ZZ	Extirpation of matter from left common iliac vein, percutaneous approach
06CF3ZZ	Extirpation of matter from right external iliac vein, percutaneous approach
06CG3ZZ	Extirpation of matter from left external iliac vein, percutaneous approach
06CM3ZZ	Extirpation of matter from right femoral vein, percutaneous approach
06CN3ZZ	Extirpation of matter from left femoral vein, percutaneous approach

In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The previously listed ICD–10–PCS procedure codes were used to identify claims involving percutaneous procedures. The claim search conducted by the applicant resulted in 15,580 claims mapping to six MS–DRGs: 270 (Other Major Cardiovascular Procedures with MCC), 271 (Other Major Cardiovascular Procedures with CC), 272 (Other Major Cardiovascular Procedures without CC/MCC), 163 (Major Chest Procedures with MCC), 164 (Major Chest Procedures with CC), and 165 (Major Chest Procedures without CC/MCC).

The applicant determined an average unstandardized case weighted charge per case of $126,211.

The applicant did not remove charges for prior technology. The applicant stated that no prior technology is being replaced. The applicant then standardized the charges using the FY 2019 Final Rule with Correction Notice Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used what it stated was the national average CCR for the Supplies and Equipment cost center of 0.299 from the FY 2021 IPPS final rule. However, we note that the actual value for this cost center for FY 2021 was 0.297. The applicant calculated a final inflated average case-weighted standardized charge per case of $180,036, which exceeded the average case-weighted threshold amount of $126,211 by $53,825. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

We invite public comment on whether INDIGO® with Lightning meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the INDIGO® with Lightning represents a substantial clinical improvement over existing technologies because it results in lower rates of aspirated blood loss during the procedure, low major bleeding event rate, reduces blood loss, reduces ICU stays, and reduces procedure time. The applicant also suggested that the technology allows for revascularization without thrombolytics and no recurrence of pulmonary embolism after 30 days.

To support its application, the applicant submitted a reference to the EXTRACT–PE prospective, single-arm study across 22 sites comparing the use of INDIGO® without Lightning to systemic thrombolysis in 119 patients with PE who had not been previously treated with anti-thrombolytics or an adjunctive device within 48 hours. The applicant stated that this study was completed under FDA Investigational Device Exception (IDE) G170064. The applicant claimed that the EXTRACT–PE study showed the INDIGO® without Lightning led to a significant mean reduction of 0.43 in right ventricle/left ventricle (RV/LV) ratio (a measure associated with poor clinical outcomes when greater than 1) that corresponded to a 27.3 percent reduction at 48 hours after intervention. They also cited a low major adverse event composite rate of 1.7 percent within 48 hours, device usage of only 37 minutes and median ICU length of stay of 1 day. According to the applicant, rates of cardiac injury, pulmonary vascular injury, clinical deterioration, major bleeding, and device-related death at 48 hours were 0%, 1.7%, 1.7%, 1.7%, and 0.8%, respectively.

The applicant cited a poster of an unpublished retrospective case review study by Hastings [290] of 18 patients with DVT treated with INDIGO® followed by anticoagulation. Primary technical success (defined as restoration of blood flow with minimal residual thrombus (<10%) without the need for a second session of treatment) was achieved in 15 patients. Three patients required adjunctive methods for successful clearance of thrombus, undergoing two sessions of treatment. Two patients had recurrence of DVT following single-session treatment, both of whom were asymptomatic at time of diagnosis.

The applicant cited the PRISM study,[291] a single-arm, multicenter, retrospective analysis of 79 patients with arterial occlusion from 2018, to provide evidence that use of INDIGO® with Lightning has a low major bleeding event rate, can result in revascularization without thrombolytics, and causes no clinically significant distal embolization. The applicant also stated that the interim results of the INDIAN study, a prospective trial using INDIGO® without Lightning to treat patients with ALI showed no device-related adverse events or major bleeding complications.[292]

The applicant asserted that an unpublished laboratory bench test using water found that the 20.3 mL/sec average flow rate of catheter with Lightning generates 18-fold reduction in blood loss when compared to the use of the same catheter and Penumbra engine pump without the Lightning technology. The applicant asserted that a bench test showed that the Penumbra aspiration pump demonstrates continuous pressure, as evidenced by a sustained -29 inHg (inches of Mercury) through 60 seconds versus a 60-ml syringe which starts at -27 Hg and drops to 0 in Hg within 18 seconds.

The applicant also asserted that an abstract of a single-center retrospective case-control trial of 38 patients by Muck, P., et al. comparing two versions of INDIGO® catheters (12F and 8F) showed that median blood loss was 250mL in the larger Lightning 12F arm (n=9, larger catheter) and 375mL in the 8F arm without Lightning (n=27, smaller catheter). Technical success (defined as greater than 70 percent thrombus reduction) was achieved in 77 percent of patients in the Lightning 12F arm compared to 18.5 percent in the 8F arm without Lightning. The applicant also asserted that this study showed that none (0/9) of the patients in the INDIGO® with Lightning group required post-procedure transfusion, whereas 18.5 percent (5/27) of the INDIGO® without Lightning group required post-procedure transfusion.

We note that in its application, the applicant did not explicitly state what the comparator was for each of its claims in support of substantial clinical improvement; for example, whether INDIGO® is being compared to systemic thrombolysis, percutaneous catheter directed thrombolysis, or other aspiration thrombectomy catheters. Comparing INDIGO® to a medical treatment modality may not be appropriate since percutaneous interventions for PE and DVT have different clinical indications, risks, and benefits compared to medical or surgical interventions.

We also note that the applicant relies mostly on studies of INDIGO® without Lightning to substantiate its claims regarding INDIGO® with Lightning. Of all the studies provided by the applicant, only one small, unpublished study of DVT patients by Muck, P., et al. includes patients treated with INDIGO® with Lightning (which has the intelligent aspiration) versus earlier versions of the applicant's device. The applicant did not demonstrate superior outcomes using INDIGO® with Lightning compared to INDIGO® without Lightning.

We note that outcomes for INDIGO® for the rates of pulmonary vascular injury at 48 hours, clinical deterioration, major bleeding and device-related deaths were stated by the applicant as low compared to systemic thrombolysis, but were not compared to outcomes for existing aspiration thrombectomy devices which may be a more appropriate comparator. We further note that in the poster study, all patients were maintained on anticoagulation following thrombectomy with INDIGO®, so it is difficult to assess the DVT

[290] Hastings, L.H., Perkowski, P.E. Single Session Percutaneous Mechanical Aspiration Thrombectomy for Symptomatic Proximal Deep Vein Thrombosis. Poster.

[291] Saxon, R.R., Benenati, J.F., Teigen, C., Adams, G.K., Sewall, L.E., and Trialists, P. (2018). Utility of a power aspiration-based extraction technique as an initial and secondary approach in the treatment of peripheral arterial thromboembolism: Results of the multicenter prism trial. *J Vasc Interv Radiol.* 29(1): p. 92–100

[292] Donato, et al. Acute Lower Limb Malperfusion—(INDIAN) Registry: Protocol (as presented at VEITHsymposium 2019).

recurrence rate (using INDIGO® alone) to support the claim that INDIGO® can be used with patients with high risk of bleeding.

We also note that suction generated through a vacuum may not be superior to other mechanisms of generating negative pressure used in other existing aspiration catheters. A study comparing suction forces and vacuum pressure of Penumbra pump to a 60-mL syringe and pumps manufactured by several other manufacturers showed that all catheters transmit similar vacuum pressure regardless of pump or 60-mL syringe.[293]

Finally, we question whether there is enough evidence to support that ''intelligent aspiration'' associated with INDIGO with Lightning provides a substantial clinical improvement over existing aspiration catheters from INDIGO® and existing devices where the aspiration is controlled manually. No direct comparison of blood loss between INDIGO® with Lightning catheter and existing aspiration thrombectomy devices from other manufacturers was provided, specifically catheters that reduce blood loss by returning the aspirated blood back to the patient. The unpublished bench test included with the application may have demonstrated a reduction in average volume of water aspirated using the INDIGO® Catheter with Lightning fully functional compared to the INDIGO® catheter with Lightning deactivated (valve pin fixed to the open position). However, this study was not designed to compare blood loss during a thrombectomy procedure between aspiration controlled by a human versus by the Lightning ''intelligent aspiration.''

We invite public comment on whether INDIGO® with Lightning meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for INDIGO® with Lightning or at the New Technology Town Hall meeting.

j. Ischemia Care Respiratory and Stroke Test Kit or ISC–REST

Ischemia Care submitted an application for new technology add-on payment for Ischemia Care Respiratory and Stroke Test Kit (ISC–REST) for FY 2022. Per the applicant, ISC–REST is a test kit composed of three tests to stratify the cause of ischemic strokes by differentiating those that originate in the heart, called cardioembolic (CE) strokes, and those that originate in the arteries, called large artery atherosclerotic (LA) strokes, once it has been determined that a patient has not suffered a hemorrhagic stroke. According to the applicant, ISC–REST is made up of three tests: (1) ISCDx, (2) the QIAstat-Dx Respiratory SARS–CoV–2 Panel, and (3) the QIAGEN Access Anti-SARS–CoV–2 Total Test. According to the applicant, the three test results provide information related to the cause of ischemic stroke and coronavirus disease 2019 (COVID–19) status to prevent a recurrent stroke. Per the applicant, the first of the three tests, ISCDx, is a blood test that uses RNA expression from whole blood to differentiate between CE and LA stroke, two types of ischemic stroke. According to the applicant, once blood is drawn, the RNA expression in the blood sample is analyzed and matched to the gene expression signatures and patterns associated with CE stroke and LA stroke. Per the applicant, the second test, the QIAstat-DX respiratory SARS–CoV–2 Panel, is a multiplexed nucleic acid real-time polymerase chain reaction (PCR) test intended for the qualitative detection and differentiation of nucleic acid from 22 respiratory pathogens, including the SARS–CoV–2 virus, in nasopharyngeal swabs. According to the applicant, the third test is the QIAGEN Access Anti-SARS–CoV–2 Total Test, a rapid, digital lateral flow serological test to detect antibodies to SARS–CoV–2 in human serum and plasma.

According to the applicant, the ISC–REST kit is intended to be used when a patient presents at the hospital with an ischemic stroke, within 30 hours of symptom onset and with a National Institutes of Health Stroke Scale (NIHSS) score of ≥5. The NIHSS measures stroke-related neurologic deficit and has predictive validity for long-term stroke outcome.[294] Per the applicant, the ISC–REST kit is intended for use at the time of the standard evaluation, at the same time that normal blood samples are collected when a patient is admitted to the hospital for stroke. According to the applicant, to use the ISC–REST kit, blood is drawn into a PaxGene tube (for the ISCDx test), a nasal swab is obtained (for the QIAstat-Dx Respiratory SARS–CoV–2 Panel), and an additional blood sample is drawn (for the QIAGEN Access Anti-SARS-CoV–2 Total Test). Per the applicant, the hospital sends all three samples to a single laboratory, the Clinical Laboratory Improvement Amendments (CLIA) certified Ischemia Care laboratory, for processing and reporting. According to the applicant, three results are reported: (1) A result for whether the gene expression in the blood sample was consistent with CE stroke or LA stroke, (2) a result for respiratory screening that includes COVID–19, influenza, and other respiratory illnesses, and (3) a result for COVID–19 antibodies to determine whether the patient previously had COVID–19.

According to the applicant, the number of cryptogenic ischemic strokes, or ischemic strokes where the cause is unknown, is concerning. The applicant states that there are 695,000 ischemic strokes each year in the United States, with 185,000 of these events being recurrent strokes. Per the applicant, for up to 40% of ischemic strokes, or roughly 250,000 ischemic strokes, the cause is cryptogenic.[295] The applicant states that when the cause of stroke is identified, secondary stroke prevention protocols may be adapted to prevent a bigger, more costly, and severe recurrent stroke. The applicant explains that cryptogenic stroke leads to high recurrence risk in cases of undetected atrial fibrillation. The applicant also explains that typically the diagnosis of the causes of stroke is complex, inconsistent across hospitals, expensive, and inconclusive. Further, the applicant claims that the cryptogenic rate is higher for stroke patients with COVID–19 than stroke patients without COVID–19, citing a retrospective study of patients hospitalized at a major New York health system between March and April 2020 that found that the cryptogenic rate was 65% for COVID–19 positive patients.[296] In that study, out of 3,556 patients that were hospitalized and diagnosed with COVID–19 during that time, 32 patients or under 1% of the sample size experienced an ischemic stroke. The study found that the standard stroke diagnostic workup did not establish the ischemic stroke etiology for a significant proportion of patients in the study with concurrent

[293] Froehler, M.T. (2017). Comparison of vacuum pressures and forces generated by different catheters and pumps for aspiration thrombectomy in acute ischemic stroke. Interventional neurology, 6(3–4), 199–206.

[294] Schlegel, Daniel et al., ''Utility of the NIH Stroke Scale as a Predictor of Hospital Disposition,'' *Stroke,* 2003;34:134–137, *https://doi.org/10.1161/01.STR.0000048217.44714.02.*

[295] Saver, Jeffrey L., ''Cryptogenic Stroke,'' *N Engl J Med,* May 26, 2016, [374:2065–2074] DOI: 10.1056/NEJMcp1503946, available at: *https://www.nejm.org/doi/10.1056/NEJMcp1503946.*

[296] Shadi Yaghi, et al. SARS–CoV–2 and Stroke in a New York Healthcare System, *Stroke.* 2020; 51:2002–2011. DOI: 10.1161/STROKEAHA.120.030335, available at: *https://www.ahajournals.org/doi/10.1161/STROKEAHA.120.030791.*

COVID–19 infection and ischemic stroke: cryptogenic stroke diagnosis was twice more prevalent in COVID–19-positive patients (65.6%), compared with both COVID–19-negative contemporary stroke patients (30.4%) and ischemic stroke patients hospitalized in the same hospital system during the same time period the year prior (25.0%).

While the applicant states in the application that there is no standard of care pathway to determine the cause of stroke, a stroke patient presenting at the hospital is typically evaluated using a standard evaluation that includes imaging and hematologic testing to determine if the patient is a candidate for intervention. Diagnosing the cause of stroke, per the applicant, often requires expensive testing, risk to the patient, and invasive procedures, without a guarantee of a definitive diagnosis. The applicant explains that each suspected cause requires a focused workup to confirm the suspicion. Additionally, the applicant points out, a negative result in one pathway does not mean a positive result in another pathway. The applicant claims that the inability to accurately stratify patients by cause of stroke often results in either limiting use of advanced patient testing or performing too many tests. The applicant further claims that diagnosing the cause of stroke and preventing recurrent stroke using a standard evaluation is even more challenging for ischemic stroke patients with COVID–19 because these patients are presenting at younger ages and without traditional comorbidities, eliminating many of the traditional causes of stroke.

While the applicant states that it is unclear to clinicians whether COVID–19 is a separate cause of stroke or aggravates comorbidities to cause a stroke, the applicant claims that the information that the ISC–REST kit would provide is important, as clinicians currently know very little about the vascular effects of COVID–19. The applicant states that the ISC–REST kit ties all of the clinical diagnosis pieces together: Respiratory viral and bacterial organism presence, COVID–19 antibody presence, and CE or LA stroke. Per the applicant, this combined testing is convenient for the clinician and also raises awareness about the COVID-stroke connection by providing real world evidence.[297] [298] Additionally, the applicant explains that traditional diagnosis of ischemic stroke cause is often complex, inconsistent, expensive, inconclusive and may require more invasive diagnosis procedures, such as implantable cardiac monitoring or transcranial doppler. Ultimately, according to the applicant, the traditional process to stratify the cause of stroke may require months or years of additional tests post event.

With respect to the newness criterion, each of the three tests in ISC–REST, as well as the ISC–REST test kit as a whole, have varying FDA authorization statuses and separate indications. The applicant stated in their application that they are seeking Emergency Use Authorization (EUA) from the FDA for the ISC–REST test kit. The applicant shared that the intended indication of ISC–REST is to provide three critical diagnostic tests in the same kit for convenience of the user during the COVID–19 public health emergency. For the ISCDx test, the applicant stated that the test had completed the requirements of the Clinical Laboratories Improvement Amendments (CLIA) analytical validations and is available as a Laboratory Developed Test. ISCDx's intended indication is to aid in the diagnosis of CE and LA stroke, when hemorrhagic stroke is ruled out, in conjunction with standard clinical evaluation and in the context of the patient's clinical history and other diagnostic test results. The test could also be used as part of the clinical evaluation and patient risk assessment. The QIAstat-Dx Respiratory SARS–CoV–2 Panel was granted an EUA on March 30, 2020 and is intended for patients suspected of COVID–19 by their healthcare provider for the detection and differentiation of nucleic acid from SARS–CoV–2 and the following organism types and subtypes: Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, SARS–CoV–2, Human Metapneumovirus A+B, Influenza A, Influenza A H1, Influenza A H3, Influenza A H1N1/pdm09, Influenza B, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Rhinovirus/Enterovirus, Respiratory Syncytial Virus A+B, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae. The applicant states that results are for the identification of SARS–CoV–2 RNA, however, negative results do not preclude SARS–CoV–2 infection and should not be used as the sole basis for patient management decisions. According to the applicant, there is no EUA request pending approval for the QIAGEN Access Anti-SARS–CoV–2 Total Test.

The applicant stated that there are currently no ICD–10–PCS procedure codes that uniquely identify the use of ISC–REST. The applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology beginning FY 2022. The applicant provided 81 ICD–10–PCS codes that they stated could be used to identify cases involving the use of ISC–REST in the interim. These 81 ICD–10–CM diagnosis codes are associated with cerebral infarctions, occlusions, and other neurological conditions consistent with ischemic stroke presentations.

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, there are no blood tests for stroke or its causes. The applicant also stated that there is no blood testing for the cause of stroke combined with COVID–19 screening.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG when compared to an existing technology, the applicant stated that the ISC–REST kit is not replacing an existing technology and reiterated that ISCDx is a blood test that stratifies ischemic stroke patients into CE and LA stroke causes The applicant stated that the technology would map to MS–DRGs 061,062, 063, 064, 065, 066, 067, 068 and that it is not requesting for ISC–REST to map to a new or different MS–DRG for FY 2022.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that there are no existing technologies to stratify stroke populations by cause.

We note the following concerns regarding whether the applicant meets the newness criterion. Under the regulations at 42 CFR 412.87(e)(2), CMS only considers, for add-on payments for a particular fiscal year, an application for which the new technology has received FDA marketing authorization by July 1 prior to the particular fiscal year. While the applicant stated that ISCDx, one of the three tests in ISC–REST test kit, has completed the requirements of the Clinical Laboratories Improvement

[297] Patients with Coronavirus Disease 2019 (COVID–19) vs Patients With Influenza, JAMA Neurol. 2020;77(11):1366–1372.

[298] COVID–19 Is an Independent Risk Factor for Acute Ischemic Stroke, American Journal of Neuroradiology, August 2020, 41(8):1361–1364.

Amendments, we note that this is not considered FDA marketing authorization as required in our regulations for the new technology add-on payment.[299]

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

As previously summarized, the applicant is seeking an EUA from the FDA for the ISC–REST test kit. An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have an FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

We also refer the reader to our comment solicitation in section II.F.7 of the preamble of this proposed rule regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA.

Additionally, we are uncertain whether the mechanism of action of ISC–REST can be considered new. While the applicant claims that there is currently no other blood test available that identifies the cause of ischemic stroke through RNA biomarkers, we note that clinicians may order blood tests as part of the stroke consultation to gather information about stroke risk factors and other medical problems which may have caused the stroke.[300] In addition, we note that there are several types of RNA biomarker tests for stroke that have been developed and used in other settings, and we therefore note that this may not represent a new mechanism of action for ISC–REST. Similarly, we are not certain whether the QIAstat-Dx Respiratory SARS–CoV–2 Panel and QIAGEN Access Anti-SARS–CoV–2 Total Test components of ISC–REST have unique mechanisms of action, as they may be similar to other PCR nasal swabs and serology tests for COVID–19 that are currently in use during the COVID–19 public health emergency. We welcome public comment regarding whether ISC–REST has a unique mechanism of action even if some or all of its test components do not have unique mechanisms of action individually. Because ISC–REST delivers three separate test results through three separate tests, it is unclear whether the combination of the tests in one kit could be viewed as representing a unique mechanism of action over and above the mechanisms of action of the tests if they were to be performed separately.

With regard to whether the technology maps to the same or different MS–DRG as existing technologies, though the applicant did not state whether it believes the technology meets this criterion, we believe that under the proposed indication for ISCDx, ISC–REST would not be used until a patient had a confirmed ischemic stroke. Therefore, under the proposed indication, it seems that the technology would map to the same MS–DRGs as cases involving the standard of care for ischemic stroke and cerebral infarction. However, it appears that there may be scenarios where a patient has an occlusion or some other neurological condition that makes the patient present with stroke-like symptoms, without having had a stroke or infarction. We invite comments on whether, for this reason, cases involving the use of the technology may be assigned to the same or different MS–DRGs as cases not only involving the standard of care for ischemic stroke and cerebral infarction, but also nonspecific cerebrovascular accidents and pre-cerebral occlusions.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, we note the applicant's statement that there are no existing technologies to stratify stroke populations by cause does not address whether the technology meets this criterion. CMS requests comments on whether ISC–REST kit would be used as a diagnostic aid in the treatment of similar diseases and patient populations as the current standard-of-care ischemic stroke diagnosis evaluation.

We are inviting public comments on whether ISC–REST is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis. The applicant used claims data from one hospital system, made up of

[299] 42 CFR 412.87(e)(2).

[300] Mayo Clinic Staff, Stroke Diagnosis, Feb. 9, 2021, *https://www.mayoclinic.org/diseases-conditions/stroke/diagnosis-treatment/drc-20350119*.

three hospitals with a total of 87 health care providers. The average percentage of patients across the three hospitals with Medicare or Medicare Advantage coverage was 69%, per the applicant. The applicant stated that raw data was provided from January 2020 through September 2020, then annualized for 2020. Per the applicant, the average standardized charges were calculated per MS–DRG by the hospital system that provided the data.

As mentioned previously, the applicant stated that the technology would map to the following MS–DRGs: MS–DRG 061 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC), 062 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with CC), 063 (Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent without CC/MCC), 064 (Intracranial Hemorrhage Or Cerebral Infarction with MCC), 065 (Intracranial Hemorrhage or Cerebral Infarction with CC or TPA in 24 Hours), 066 (Intracranial Hemorrhage or Cerebral Infarction without CC/MCC), 067 (Nonspecific CVA And Precerebral Occlusion without Infarction with MCC), and 068 (Nonspecific CVA And Precerebral Occlusion Without Infarction Without MCC). The applicant's data included a total of 385 cases mapping to those MS–DRGs. The applicant did not submit claims data for two of the listed MS–DRGs, MS–DRG 063 and 067, because the data source that the applicant used did not have any cases under those MS–DRGs for the time period that the sample data was collected. The applicant imputed 11 claims for two other MS–DRGs, 061 and 068, because there were fewer than 11 claims submitted for these MS–DRGs.

The applicant stated that it compared the distribution of MS–DRGs in the hospital data to the distribution of MS–DRGs in the FY 2022 New Technology Add-On Payment thresholds, which includes the number of cases per MS–DRG. The applicant asserted that because the MS–DRG distributions were highly similar, the data sample obtained from the hospital system was representative of the distribution of MS–DRGs nationally.

The applicant did not remove charges for a prior technology because, as the applicant noted, ISC–REST is not replacing any other technology. The applicant then applied the one-year charge inflation factor of 1.06353 included in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 59039) to inflate the charges from FY 2020 to FY 2021. To add charges for the new technology, the applicant multiplied the cost of ISC–REST by the cost-to-charge ratio for acute care hospitals found in the FY 2020 IPPS/LTCH PPS final rule. The applicant explained that the urban and rural hospital cost-to-charge ratios were combined to yield a national average of 0.3095. However, we note that the applicant appears to have used the cost-to-charge ratios in Table 8A, which lists the statewide average operating cost-to-charge ratios for acute care hospitals.

The applicant calculated a final inflated average case-weighted standardized charge per case of $87,842 which exceeds the average case-weighted threshold amount, $57,110. The applicant contended that ISC–REST meets the cost criterion based on these analyses.

We have the following concerns regarding the cost criterion. It is not clear whether the applicant's use of private data from three hospitals is representative of the Medicare population. While the applicant states that the average Medicare and Medicare Advantage percentage of patients across the 3 hospitals was 69%, CMS is unsure whether the claims under the MS–DRGs the applicant provided are for Medicare patients, or private insurance patients in those hospitals. Similarly, because the applicant annualized data from the months of January to September 2020, it is not clear whether the portion of time selected by the applicant is representative of the entire year. Additionally, while the applicant points to the fact that the sample of claims data from the 3 hospitals had similar MS–DRG distributions as the FY 2022 New Technology Add-on Payment Thresholds, it is not clear whether this would indicate that the charging practices of the hospitals or their patient costs are similar to Medicare claims data nationally. It is also not clear whether the applicant's cost analysis is representative of the cost of the technology as the applicant did not use the applicable cost-to-charge ratio of 0.107 for laboratory services as provided in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). Finally, we note that it is not possible for CMS to verify the claims data submitted, as the applicant used hospital claims data that is not publicly available and did not identify the source. We are inviting public comments on whether ISC–REST meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that ISC–REST represents a substantial clinical improvement over existing technologies for several reasons. First, the applicant asserts that ISC–REST has the ability to stratify ischemic stroke patients early in the diagnosis process to reduce the number of cryptogenic stroke diagnoses, which leads to appropriate medical management that can better reduce the risk of a recurrent stroke. Second, the applicant asserts that ISC–REST will lead to appropriate utilization of subsequent diagnostic testing, or decrease the necessary use of subsequent diagnostic testing, to determine stroke etiology, including: Implantable cardiac monitoring, hypercoagulation panels, magnetic resonance angiography, and other commonly used tests for ischemic stroke. Third, the applicant asserts that use of ISC–REST will lead to a reduction in at least one clinically significant adverse event, a recurrent stroke, including a reduction in mortality or a clinically significant complication. Fourth, the applicant further asserts that use of ISC–REST will result in a decreased use of, or more appropriate utilization of, therapeutic intervention, in cases where patients are medically managed for a comorbidity and a stroke occurs. Fifth, the applicant asserts that use of ISC–REST will result in a decreased number of future hospitalizations by reducing recurrent stroke risk and physician visits, as in some cases ISC–REST will result in a diagnosis pathway that will not require surgical or invasive procedures. Additionally, once ISC–REST identifies the cause of the stroke, the applicant asserts that the opportunity to manage a chronic population may include telemedicine approach, rather than in-person physician visits. Finally, the applicant asserts that ISC–REST will result in improved quality of life by helping avoid a recurrent stroke.

The applicant submitted five information sources to address the substantial clinical improvement criterion, as well as supplementary information in the application itself and additional narrative responses. First, the applicant submitted a poster presentation by Jauch E.C., on the results and methodology of a Biomarkers of Acute Stroke Etiology (BASE) study to determine whether RNA expression can accurately differentiate LA stroke from CE stroke in the acute setting.[301] Similarly, the applicant submitted an unpublished manuscript detailing another BASE study on stroke biomarkers to determine

[301] Jauch, Edward C., on behalf of BASE clinical trial principal investigators, ''RNA Expression for Diagnosis of Stroke Etiology Differentiating Large Artery and Cardioembolic Stroke: Analytical Validation of Testing From the BASE Clinical Trial,'' 2020 AHA International Stroke Conference.

if the etiology of acute ischemic stroke could be objectively determined by RNA expression using BASE blood samples.[302] Third, the applicant submitted a published study methodology paper by Jauch et al., on the methodology of an ongoing (at the time of publication) BASE study to identify serum markers defining the etiology of acute ischemic stroke.[303] The fourth information source, by Jickling et al., was a published article from 2010 on a study to design genetic probes for ischemic stroke. The fifth and final information source submitted was a 2016 journal article by Jeffrey L. Saver, with background information on etiologies of stroke.[304]

The first three information sources all describe the BASE trial (NCT02014896), a prospective, multicenter, observational, convenience, sample cohort study of patients presenting to the hospital within 24 hours of stroke onset, which looked to determine if the etiology of acute ischemic stroke can be objectively determined by RNA expression from patient blood samples.[305] [306] [307] The primary objective of the BASE study was to confirm the diagnostic accuracy of the ISCDx test to identify stroke subtypes in patients with acute ischemic stroke. According to the BASE Study Methodology paper by Jauch et al., while enrollment for this multisite study was ongoing at the time of publication, it was expected to hit 1000 patients by March 2017.[308] The Base Study Methodology paper explains that blood samples were first collected from patients presenting to the hospital within 24 hours of stroke onset, and then again collected 24 hours and 48 hours later.[309] The tubes were kept at room temperature for up to 24 hours and then frozen −20 °C until shipped to the Ischemia Care CLIA laboratory where the ISCDx testing was performed. From these blood samples, RNA gene expression was utilized to identify stroke etiology marker candidates. Patients who met the inclusion criteria: (1) Had experienced a suspected acute ischemic stroke within 24(+/−6) hours of symptom onset; (2) had a normal baseline CT, without hemorrhage or alternate explanation for symptoms; (3) were older than 18 years old; and (4) gave informed consent. Control samples consisted of 100 non-stroke Emergency Department patients matched on clinical risk factors of age, race, gender, smoking history, diabetes, hypertension, atrial fibrillation, and hyperlipidemia. We note that there are changes from the previously stated study methodology in the two sources the applicant included with BASE study results.[310] [311] For example, while the study methodology as described in the Jauch et al. paper stated that the blood samples were kept at room temperature for up to 24 hours and then frozen,[312] in the poster presentation by Jauch, E.C., the samples were frozen within 72 hours of collection.[313]

The applicant describes a set of study results, which are detailed in the unpublished manuscript by Peacock et al. and the poster presentation by Jauch, E.C.[314] [315] These analyses used adjudicated stroke diagnoses, classified as CE and LA, and determined by two board-certified neurologists blinded to each other's diagnosis and biomarker results. The 218 patients enrolled were randomly assigned to a derivation cohort (70%) or validation cohort (30%). Using the derivation set gene expression levels, a signature was created to distinguish between CE and LA ischemic stroke, with the derived model then applied to the validation cohort. 59% of the participants in the study were male with a median age of 70.7 years. The median time from symptom onset to blood collection was 1200 minutes (ranging from 448 to 1568 minutes). The applicant explains that, of the 218 patients enrolled with an NIHSS>5, 149 were adjudicated as CE and 69 were adjudicated as LA. Additionally, sample analysis of the derivation cohort resulted in 9,513 unique gene-level probe-sets for signature inclusion, with the best set containing 45 genes. The diagnostic gene signature results in the early validation cohort distinguished CE stroke from LA stroke with a C-statistic of 0.78 (0.50–1.0, 95% CI), sensitivity of 0.90 and specificity of 0.70. The study concluded that RNA expression accurately identifies stroke etiology.

The applicant also provided the following supplemental information to support that combining three tests in the ISC–REST kit improves patient outcomes over performing the lab tests separately. Though the applicant noted that there is no direct evidence currently available regarding the impact of using the ISC–REST kit, they explain that, in their experience, clinical supporters of the ISC–REST kit claim that they would order ISC–REST kit testing 100% of the time versus ordering three separate tests. The applicant claims that there is a convenience, cost effectiveness, and time savings associated with ISC–REST during a time when hospital resources are limited. Second, the applicant states that because the QIAstat-Dx Respiratory SARS–CoV–2 Panel tests for COVID–19 as well as 12 other common respiratory illnesses, in testing for several respiratory illnesses, ISC–REST may inform care decisions. Third, the applicant states that collecting the samples for each test together and testing them in the same laboratory will ensure high levels of quality control. The applicant also claims that using the ISC–REST test kit has investigative benefits, including the ability to help track and study how long the COVID–19 antibodies last in a chronic population based upon consistent measurement of the index events (stroke and COVID–19). Finally, the applicant states that the ISC–REST kit and adoption of guideline-directed appropriate care will result in prevention of recurrent strokes because it will impact clinician choice of therapeutics.

After a review of the information provided by the applicant, we have the

[302] Peacock, W.F. and Edward Jauch., ''Cardioembolic vs Large Artery Atherosclerotic Stroke: Can we answer Hobson's question?'', pre-publication manuscript.

[303] Jauch, Edward C., et al. ''Biomarkers of Acute Stroke Etiology (BASE) Study Methodology,'' May 5, 2017.

[304] Saver, Jeffrey L., ''Cryptogenic Stroke,'' *N Engl J Med,* May 26, 2016.

[305] Jauch, Edward C., on behalf of BASE clinical trial principal investigators, ''RNA Expression for Diagnosis of Stroke Etiology Differentiating Large Artery and Cardioembolic Stroke: Analytical Validation of Testing From the BASE Clinical Trial,'' 2020 AHA International Stroke Conference.

[306] Peacock, W.F. and Edward Jauch., ''Cardioembolic vs Large Artery Atherosclerotic Stroke: Can we answer Hobson's question?'', pre-publication manuscript.

[307] Jauch, Edward C., et al. ''Biomarkers of Acute Stroke Etiology (BASE) Study Methodology,'' May 5, 2017.

[308] Jauch, Edward C., et al. ''Biomarkers of Acute Stroke Etiology (BASE) Study Methodology,'' May 5, 2017.

[309] Ibid.

[310] Peacock, W.F. and Edward Jauch., ''Cardioembolic vs Large Artery Atherosclerotic Stroke: Can we answer Hobson's question?'', pre-publication manuscript.

[311] Jauch, Edward C., on behalf of BASE clinical trial principal investigators, ''RNA Expression for Diagnosis of Stroke Etiology Differentiating Large Artery and Cardioembolic Stroke: Analytical Validation of Testing From the BASE Clinical Trial,'' 2020 AHA International Stroke Conference.

[312] Jauch, Edward C., et al. ''Biomarkers of Acute Stroke Etiology (BASE) Study Methodology,'' May 5, 2017.

[313] Jauch, Edward C., on behalf of BASE clinical trial principal investigators, ''RNA Expression for Diagnosis of Stroke Etiology Differentiating Large Artery and Cardioembolic Stroke: Analytical Validation of Testing From the BASE Clinical Trial,'' 2020 AHA International Stroke Conference.

[314] Peacock, W.F. and Edward Jauch., ''Cardioembolic vs Large Artery Atherosclerotic Stroke: Can we answer Hobson's question?'', pre-publication manuscript.

[315] Jauch, Edward C., on behalf of BASE clinical trial principal investigators, ''RNA Expression for Diagnosis of Stroke Etiology Differentiating Large Artery and Cardioembolic Stroke: Analytical Validation of Testing From the BASE Clinical Trial,'' 2020 AHA International Stroke Conference.

following concerns with regard to the substantial clinical improvement criterion.

We note that all of the BASE study results that the applicant submitted provide information on the ISCDx test on its own rather than the ISC–REST test kit, for which the applicant has submitted an application for new technology add-on payment consideration.[316] [317] As stated in the BASE Study methodology paper by Jauch, et al., the primary objective of the BASE study is to confirm the diagnostic accuracy of the ISCDx test to identify stroke subtypes in patients with acute ischemic stroke.[318] No data were provided with regard to the complete ISC–REST kit, the other components individually, or any combination. We are therefore unclear as to whether it is possible to draw conclusions about substantial clinical improvement for the ISC–REST kit using the limited data provided on the ISCDx test and without any data or studies on the ISC–REST kit. Specifically, the applicant did not submit data or studies on how treatment decisions are impacted after the ISC–REST kit is used or if there is any impact on patient outcomes as a result of using the technology. While the applicant has made claims regarding reducing downstream diagnostic tests and avoiding inappropriate medical intervention by using the ISC–REST kit, it did not provide any studies or data regarding these claims. The applicant also made claims as to how the individual parts of the test impact care decisions, but similarly did not provide data to demonstrate this. For example, the applicant claimed that, in testing for several respiratory illnesses, the QIAstat-Dx Respiratory SARS–CoV–2 Panel will inform care decisions, but did not submit any evidence that this is the case. We also note that, because the applicant has not submitted evidence to demonstrate the utility of the ISC–REST kit, it seems that the additional tests outside of the ISCDx test could result in clinical burden and additional cost without demonstrated benefits.

With regard to the studies submitted on ISCDx, we are unsure whether they demonstrate or examine the impacts of using the test on patient care and clinical outcomes. The applicant did not submit evidence to demonstrate that a recurrent stroke did not happen, that the use of more invasive investigational or further diagnostic tools was avoided, or that there was an increase in appropriate treatment and recurrent stroke prevention protocols after using the test. In the study methodology paper by Jauch et al., the applicant did not include full survey results because they were not available at the time the application was submitted. Additionally, we are unsure how to interpret the results from the small BASE study for ISCDx because there are variations between the study methodology as explained in the Jauch, E.C. et al. paper and the way the studies were actually conducted. For example, while the study methodology as described in the Jauch et al., paper stated that the blood samples were kept at room temperature for up to 24 hours and then frozen,[319] in the poster presentation by Jauch, E.C., the samples were frozen within 72 hours of collection.[320] We also have concerns regarding the testing accuracy of the ISCDx test. In the BASE study results that were submitted on the ISCDx test, the sensitivity was 0.90 and specificity was 0.70 for a sample size of 218 survey subjects.[321] Due to these figures, we question whether ISC–REST would alter the standard care ischemic stroke patients receive. Further, we note that the only trials submitted on the ISCDx test included patients whose cause of stroke was already determined. While the applicant claims that ISC–REST has the ability to stratify ischemic stroke patients early in the diagnosis process to reduce the number of cryptogenic stroke diagnoses and more appropriately manage stroke to reduce secondary recurrence, we question if there is sufficient evidence to evaluate this claim because the cause of stroke had already been determined in the study results the applicant submitted.

The applicant stated that there is no guideline standard of care pathway to determine cause of stroke, and uses this assertion as an underlying assumption for its claims in support of substantial clinical improvement. CMS notes that while there is room for clinicians to order certain additional tests over others depending on a patient's circumstances, there are algorithms developed by professional societies for the diagnosis and treatment of ischemic stroke.[322] These best practices are updated frequently to reflect current clinical research, and detail prehospital care, urgent and emergency evaluation and treatment, and in-hospital management, including early secondary prevention measures. CMS notes that by assuming that there is no guideline standard of care to determine the cause of stroke, the applicant has not presented information to compare the technology against a standard of care or other technology to allow for an assessment of whether the technology is a substantial clinical improvement over existing technologies to diagnose the cause of stroke.

We are also unsure whether the way the ISC–REST test kit is used will limit its ability to impact any care decisions and prevent hospital use. Specifically, we question if the extended 30-hour window for obtaining the patient samples, as well as the added element of shipping the ISC–REST kit to a single laboratory, is in line with stroke protocols, which focus on diagnosing a stroke as quickly as possible to maximize patient outcomes. There has been extensive research regarding the time-outcome relationship for stroke; because brain cells die rapidly after the event of the stroke, effective treatment must start as early as possible.[323] Since every minute matters in stroke treatment and secondary prevention, we believe that clinicians may order further diagnostic tests and begin a treatment plan before the ISC–REST kit results become available, which may limit the utility of the technology and its ability to impact care decisions. In other words, CMS questions whether ISC–REST would improve or alter the standard course of treatment for ischemic stroke due to the delay in receiving test results. We further note that sending the ISC–REST test kit to an external lab may cause a delay in COVID–19 test results as well. Therefore, we remain unclear as to the clinical benefit of combining these tests and are unsure how this potential for delay in results affects the technology's ability to impact care decisions.

[316] Ibid.

[317] Peacock, W.F. and Edward Jauch., ''Cardioembolic vs Large Artery Atherosclerotic Stroke: Can we answer Hobson's question?'', pre-publication manuscript.

[318] Jauch, Edward C., et al. ''Biomarkers of Acute Stroke Etiology (BASE) Study Methodology,'' May 5, 2017.

[319] Ibid.

[320] Jauch, Edward C., on behalf of BASE clinical trial principal investigators, ''RNA Expression for Diagnosis of Stroke Etiology Differentiating Large Artery and Cardioembolic Stroke: Analytical Validation of Testing From the BASE Clinical Trial,'' 2020 AHA International Stroke Conference.

[321] Ibid.

[322] Power, William J. ''Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association,'' *Stroke.* 2019 Dec; 50:e344 *https://doi.org/10.1161/STR.0000000000000211.*

[323] Harpaz, Dorin., et al., ''Point-of-Care-Testing in Acute Stroke Management: An Unmet Need Ripe for Technological Harvest,'' *Biosensors (Basel),* 2017 Sep; 7(3): 30. Published online 2017 Aug 3. DOI: 10.3390/bios7030030.

The applicant also submitted various narrative responses claiming that testing for COVID–19 at the same time as testing for the cause of the ischemic stroke constitutes substantial clinical improvement over existing technologies. Regarding the applicant's claims that the ISC–REST test kit is convenient for clinicians, CMS is unsure whether there is currently a need to order testing for COVID–19 along with the ISCDx test because, during the COVID–19 public health emergency, many hospitals automatically test for COVID–19 upon hospital admission to ensure proper treatment and containment. Further, CMS is unsure whether convenience for clinicians is evidence of substantial clinical improvement. With regard to the applicant's claim that, in its experience, clinical supporters of the ISC–REST kit claim that they would order ISC–REST kit testing 100% of the time versus ordering three separate tests, it is unclear whether clinical supporters of the ISC–REST kit are representative of all providers, including those participating in Medicare. Similarly, the applicant did not provide evidence to support its claim that ISC–REST will help gather data on any connection between COVID–19 and stroke, including a tracking mechanism for how long COVID–19 antibodies last, such as how ISC–REST would be better at gathering data on COVID–19 and stroke than other COVID–19 diagnostics.

Regarding the applicant's claims that knowing the results of all three tests in the ISC–REST kit, including COVID–19 status, impacts clinicians' choice of therapeutics for secondary stroke prevention or other treatment decisions, we are not sure that this conclusion can be reached as the connection between COVID–19 and stroke has not been established. As evidence of the connection between COVID–19 and stroke, the applicant claims that the cryptogenic rate is higher for stroke patients with COVID–19 than stroke patients without COVID–19 and references a study of one hospital, where 32 patients hospitalized for COVID–19 or positive for COVID–19 experienced an ischemic stroke during a one-month period of time in the spring of 2020. Other studies have been conducted researching the possible link between COVID–19 and stroke, including one study with a larger sample size, analyzing over 27,000 participants across 54 health care facilities, that suggests that stroke in COVID–19 patients is infrequent, and is associated with typical stroke risk factors.[324] Another study, analyzing data from close to 25,000 discharges from a large New York-based health care system from January to April 2020, did not identify a positive association between ischemic stroke and COVID–19.[325] Based on the information that the applicant submitted, it is also unclear whether stroke treatment for an ischemic stroke patient, who is also COVID–19 positive, would be different than for an ischemic stroke patient who is COVID–19 negative. For example, it is unclear whether a stroke patient would not receive antiplatelet or anticoagulative treatment due to a COVID–19 diagnosis. Because the connection between stroke and COVID–19 is unclear and is still in the preliminary stages of research, we are unsure whether testing for the type of ischemic stroke as well as COVID–19 status is a substantial clinical improvement over existing technologies. As stated previously, the applicant did not submit studies or data on how using the ISC–REST kit has an impact on downstream treatment decisions or patient outcomes to determine whether knowing a patient's COVID–19 status and the type of ischemic stroke they experienced is a substantial clinical improvement over existing technologies. Furthermore, as there is research that casts doubt on the connection between COVID–19 and stroke,[326] [327] we question whether placing an emphasis on COVID–19 status and stroke may discourage a clinician from continuing to investigate the cause or treat an underlying predisposing condition for stroke, once the patient has recovered from COVID–19, and whether this could potentially lead to negative patient outcomes.

We are inviting public comments on whether ISC–REST meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ISC–REST.

j. Lifileucel

Iovance Biotherapeutics submitted an application for new technology add-on payments for lifileucel for FY 2022. According to the applicant, lifileucel is a proprietary, one-time autologous Tumor Infiltrating Lymphocytes (TIL) cell-based therapy being studied for effectiveness in solid tumors. TIL cell therapy with lifileucel involves the adoptive cell transfer (ACT) of autologous T-cells directly isolated from the tumor tissue and expanded ex vivo without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the infusion of lifileucel, the TIL migrate back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens.

According to the applicant, relapsed and refractory metastatic melanoma presents a high unmet medical need with low survival rates and limited durable treatment options.[328] Despite the advances in available treatments, responses in patients with metastatic melanoma are at times inadequate, with many patients either not responding (40% to 65%) [329] [330] or displaying primary or acquired resistance (>70%) and the disease progresses.[331] [332] [333] [334] [335] The applicant

[324] Qureshi, et al. ''Acute Ischemic Stroke and COVID–19: An Analysis of 27,676 Patients,'' *Stroke,* 4 Feb 2021, *https://www.ahajournals.org/doi/abs/10.1161/STROKEAHA.120.031786*.

[325] Bekelis, et al. Ischemic Stroke Occurs Less Frequently in Patients With COVID–19: A Multicenter Cross-Sectional Study, *Stroke,* 51(12):3570–3476, 27 Oct 2020, *https://pubmed.ncbi.nlm.nih.gov/33106109/#affiliation-1*.

[326] Qureshi, et al. ''Acute Ischemic Stroke and COVID–19: An Analysis of 27,676 Patients,'' *Stroke,* 4 Feb 2021, *https://www.ahajournals.org/doi/abs/10.1161/STROKEAHA.120.031786*. Qureshi, et al., 2021, Ibid.

[327] Bekelis, et al. Ischemic Stroke Occurs Less Frequently in Patients With COVID–19: A Multicenter Cross-Sectional Study, *Stroke,* 51(12):3570–3476, 27 Oct 2020, *https://pubmed.ncbi.nlm.nih.gov/33106109/#affiliation-1*. Bekelis, et al., 2020, Ibid.

[328] Sarnaik A, et al. Safety and efficacy of lifileucel (LN–144) tumor infiltrating lymphocyte therapy in metastatic melanoma patients after progression on multiple therapies—independent review committee data update. Poster presented at SITC 2019. Poster Number: P865 and abstract; Journal: J Immunotherapy Cancer 2020;8:A12.

[329] Mooradian MJ and Sullivan RJ. What to do when anti-PD–1 therapy fails in patients with melanoma. Oncology (Williston Park) 2019;33:141–8.

[330] Gide TN, et al. Primary and acquired resistance to immune checkpoint inhibitors in metastatic melanoma. Clin Cancer Res 2018;24:1260–70.

[331] Luke JJ, et al. Targeted agents and immunotherapies: Optimizing outcomes in melanoma. Nature Reviews Clinical Oncology. Doi:10.1038/ncrclinonc.2017.43. Published online April 4, 2017.

[332] Mooradian MJ and Sullivan RJ. What to do when anti-PD–1 therapy fails in patients with melanoma. Oncology (Williston Park) 2019;33:141–8.

[333] Gide TN, et al. Primary and acquired resistance to immune checkpoint inhibitors in

stated there are currently no approved agents for the treatment of patients with metastatic melanoma who fail available standard-of-care therapies, which include immune checkpoint inhibitors (ICI) and BRAF/MEK inhibitors. According to the applicant, the only commonly used available therapy for these patients post progression is chemotherapy. The applicant stated that as demonstrated in the literature referenced previously, retreatment with chemotherapy [336] [337] [338] or experimental combined ICIs [339] offers a poor Objective Response Rate (ORR) [340] of 4%–10%,[341] [342] a median PFS of 2.7–3.7 months [343] [344] [345] and a median OS of ~7–8 months.[346] [347]

With respect to the newness criterion, the applicant stated that they are currently awaiting FDA approval of the Biologics License Application (BLA) for lifileucel as an autologous TIL immunotherapy indicated for the treatment of patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD–1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. The applicant stated that currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving lifileucel. We note that the applicant has submitted a request for approval for a unique ICD–10–PCS code for the administration of lifileucel beginning in FY 2022.

If a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that lifileucel is not the same or similar to the mechanism of action of currently available products used in the treatment of advanced melanoma. According to the applicant, prior to 2011, the most common first-line treatment for patients with Stage III unresectable or Stage IV unresectable metastatic melanoma was single-agent therapy using dacarbazine (DTIC) or another alkylating agent, or combination chemotherapy using DTIC together with a platinum-based drug such as carboplatin and/or a microtubule inhibitor such as paclitaxel.[348] [349] [350] IL–2 therapy has also been used as part of a biochemotherapy (BCT) antineoplastic regimen. The applicant asserted that since 2011, treatment options for advanced-stage melanoma have included kinase inhibitors such as BRAF and MEK inhibitors, cytotoxic T-lymphocyte-associated antigen 4 (CTLA–4) and programmed cell-death protein 1 (PD–1) blocking antibodies. According to the applicant, the currently available first and second line treatments for advanced melanoma include kinase inhibitors (BRAF and MEK inhibitors) and ICIs (anti-CTLA–4 antibody and anti-PD1 antibody).[351] The applicant asserts that there are no approved treatment options for patients with metastatic melanoma that have progressed after two lines of therapy.

According to the applicant, TIL cell therapy with lifileucel uses a novel and distinct mechanism of action which delivers a highly customized, personalized, and targeted treatment for unresectable or metastatic melanoma. Lifileucel TIL cell therapy involves the ACT of autologous T-cells directly isolated from the patient's tumor tissue and expanded ex vivo. Following the infusion of lifileucel, the TIL migrates back into the patient's tumor deposits, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens. According to the applicant, after approval, lifileucel will be the only personalized, cellular therapy indicated for the treatment of unresectable or metastatic melanoma.

The applicant asserted TIL cell therapy with lifileucel is also highly differentiated from currently approved chimeric antigen receptor (CAR) T-cell therapies which treat liquid tumors: YESCARTA® (axicabtagene ciloleucel) and KYMRIAH® (tisagenlecleucel), both approved for the treatment of large B-cell lymphoma in adults, and recently approved TECARTUS™ (brexucabtagene autoleucel) indicated for the treatment of relapsed/refractory mantle cell lymphoma (MCL). According to the applicant, CAR T-cell therapies mainly target only single/surface tumor antigens, versus TIL cell therapy which targets multiple tumor antigens. The applicant stated that there are no examples of successful utility of CAR T-cell therapy in solid tumors. The applicant further stated that the TIL mechanism of action does not rely on genetically engineered receptors, but maintains some physiologic control and therefore avoids hyperactivation that may be responsible for complications from CAR T-cell therapy such as cytokine release syndrome (CRS) or neurotoxicity.[352] Per the applicant,

metastatic melanoma. Clin Cancer Res 2018;24:1260–70.

[334] Schachter J, et al. Pembrolizumab versus ipilimumab for advanced melanoma: Final overall survival results of a multicenter, randomized, open-label phase 3 study (KEYNOTE–006). Lancet 2017; 390:1853–62.

[335] Ugurel S, et al. Survival of patients with advanced metastatic melanoma: The impact of novel therapies-update 2017. Eur J Cancer 2017; 83:247–257.

[336] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[337] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[338] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[339] Kirchberger MC, et al. Combined low-dose ipilimumab and pembrolizumab after sequential ipilimumab and pembrolizumab failure in advanced melanoma. Eur J Cancer. 2016;65:182–184. doi:10.1016/j.ejca. 2016.07.003.

[340] As used by the applicant and the studies provided, Objective Response Rate (ORR) is the combination of Complete and Partial Responses.

[341] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[342] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[343] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[344] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: A randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[345] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[346] Kirchberger MC, et al. Combined low-dose ipilimumab and pembrolizumab after sequential ipilimumab and pembrolizumab failure in advanced melanoma. Eur J Cancer. 2016;65:182–184. doi:10.1016/j.ejca. 2016.07.003.

[347] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[348] Gogas HD, et al. The role of taxanes in the treatment of metastatic melanoma. Melanoma Res. 2004;14(5): 415–420.

[349] Yang AS and Chapman PB. The history and future of chemotherapy for melanoma. Hematol Oncol Clin North Am. 2009;23(3): 583–597.

[350] Yushak M, et al. Advances in the systemic treatment of metastatic melanoma. Oncology (Williston Park). 2013; 27(5).

[351] Luke JJ, et al. Targeted agents and immunotherapies: Optimizing outcomes in melanoma. Nature Reviews Clinical Oncology. Doi:10.1038/ncrclinonc.2017.43. Published online April 4, 2017.

[352] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the

Continued

there have been no off-tissue effects found to date following treatment with TIL cell therapy, and TIL therefore offers a differentiated safety profile compared to CAR T-cell products or ICIs and confirms the mechanism of action differentiation discussed previously.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant stated that CMS has not yet determined the MS–DRG mapping for cellular therapies such as lifileucel. The applicant asserted that while TIL cell therapy is different from CAR T-cell therapy mechanistically, from tumor (solid vs. liquid) activity, and from a safety perspective, there are other similarities that support grouping the two technologies into a common MS–DRG for autologous T-cell immunotherapy. The applicant asserted that both CAR T-cell and TIL require collection of a patient's lymphocyte cells which are the core component of a complicated and lengthy manufacturing process to produce a patient-specific therapeutic dose. The applicant added that both are primarily administered in a hospital inpatient setting because of the risk of significant but treatable adverse events. Lastly, the applicant stated because of the complex process required to develop a personalized treatment and the total cost of caring for patients who have received TIL cell therapy that is similar to CAR T-cell therapy, these cases are expected to be comparably resource intensive.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that with FDA approval, lifileucel will be the only FDA-approved cellular treatment for patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy.

Based on the information provided by the applicant, we have several questions with regard to the newness criterion. With respect to the first criterion for substantial similarity, we note that for FY 2019 (83 FR 41299), CMS approved two CD19 directed CAR T-cell therapies, YESCARTA® and KYMRIAH®, for new technology add-on payments. The applicant asserted that CAR T-cell therapies and TIL therapies can be differentiated by multiple criteria as listed previously. We are seeking public comment on whether the mechanism of action for lifileucel is different from existing therapies, in particular whether the distinguishing criteria identified by the applicant are sufficient to differentiate the mechanism of action of TIL from CAR T-cell therapies.

We are inviting public comments on whether lifileucel is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate the technology meets the cost criterion. The applicant conducted multiple analyses to include a primary cohort, a cohort with a principle or admitting ICD–10 diagnosis of melanoma and metastasis and a cohort with any ICD–10 diagnosis of melanoma and metastasis. The ICD–10 codes and MS–DRGs identified by the applicant (for the primary cohort) are listed in the following tables.

MS-DRG Assignments for Primary Cohort	
MS-DRG	**Description**
838	Chemo w Acute Leukemia As Sdx w CC or High Dose Chemo Agent
847	Chemotherapy w/o Acute Leukemia as Secondary Diagnosis w CC
837	Chemo w Acute Leukemia as Sdx or w High Dose Chemo Agent w MCC
846	Chemotherapy w/o Acute Leukemia as Secondary Diagnosis w MCC
981	Extensive O.R. Procedure Unrelated To Principal Diagnosis w MCC
330	Major Small & Large Bowel Procedures w CC
829	Myeloproliferative Disorders Or Poorly Differentiated Neoplasms w Other Procedure w CC/MCC
939	O.R. Proc w Diagnoses of Other Contact w Health Services w MCC
029	Spinal Procedures w CC or Spinal Neurostimulators
641	Misc Disorders of Nutrition,Metabolism,Fluids/Electrolytes w/o MCC
596	Major Skin Disorders w/o MCC
542	Pathological Fractures & Musculoskelet & Conn Tiss Malig w MCC
181	Respiratory Neoplasms w CC
374	Digestive Malignancy w MCC
308	Cardiac Arrhythmia & Conduction Disorders w MCC
841	Lymphoma & Non-Acute Leukemia w CC
595	Major Skin Disorders w MCC
481	Hip & Femur Procedures Except Major Joint w CC
054	Nervous System Neoplasms w MCC
393	Other Digestive System Diagnoses w MCC

To conduct the primary analysis, the applicant identified a cohort of patients that would be eligible for lifileucel that met the criteria of having any ICD–10 diagnosis of melanoma from the following table, and any ICD–10 diagnosis of metastasis from the following table, and any ICD–10 procedure code indicating administration of IL–2 or other chemotherapy via central or peripheral vein from the following table.

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treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

Melanoma ICD-10-CM Codes	
ICD-10-CM	**Description**
C43	Malignant melanoma of skin
C43.0	Malignant melanoma of lip
C43.1	Malignant melanoma of eyelid, including canthus
C43.10	Malignant melanoma of unspecified eyelid, including canthus

Melanoma ICD-10-CM Codes	
ICD-10-CM	**Description**
C43.11	Malignant melanoma of right eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.2	Malignant melanoma of ear and external auricular canal
C43.20	Malignant melanoma of unsp ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.3	Malignant melanoma of other and unspecified parts of face
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.5	Malignant melanoma of trunk
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.6	Malignant melanoma of upper limb, including shoulder
C43.60	Malignant melanoma of unsp upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.7	Malignant melanoma of lower limb, including hip
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C438	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
D03.0	Melanoma in situ of lip
D03.10	Melanoma in situ of unspecified eyelid, including canthus
D03.11	Melanoma in situ of right eyelid, including canthus
D03.12	Melanoma in situ of left eyelid, including canthus
D03.20	Melanoma in situ of unspecified ear and external auricular canal
D03.21	Melanoma in situ of right ear and external auricular canal
D03.22	Melanoma in situ of left ear and external auricular canal
D03.30	Melanoma in situ of unspecified part of face
D03.39	Melanoma in situ of other parts of face
D03.4	Melanoma in situ of scalp and neck
D03.51	Melanoma in situ of anal skin
D03.52	Melanoma in situ of breast (skin) (soft tissue)
D03.59	Melanoma in situ of other part of trunk
D03.60	Melanoma in situ of unspecified upper limb, including shoulder
D03.61	Melanoma in situ of right upper limb, including shoulder
D03.62	Melanoma in situ of left upper limb, including shoulder
D03.70	Melanoma in situ of unspecified lower limb, including hip
D03.71	Melanoma in situ of right lower limb, including hip
D03.72	Melanoma in situ of left lower limb, including hip
D03.8	Melanoma in situ of other sites
D03.9	Melanoma in situ, unspecified

Metastasis ICD-10-CM Codes	
ICD-10-CM	**Description**
C77	Secondary and unspecified malignant neoplasm of lymph nodes
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78	Secondary malignant neoplasm of respiratory and digestive organs
C78.0	Secondary malignant neoplasm of lung
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.3	Secondary malignant neoplasm of other and unspecified respiratory organs
C78.30	Secondary malignant neoplasm of unspecified respiratory organ
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.8	Secondary malignant neoplasm of other and unspecified digestive organs
C78.80	Secondary malignant neoplasm of unspecified digestive organ
C78.89	Secondary malignant neoplasm of other digestive organs
C79	Secondary malignant neoplasm of other and unspecified sites
C79.0	Secondary malignant neoplasm of kidney and renal pelvis
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.1	Secondary malignant neoplasm of bladder and other and unspecified urinary organs
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.3	Secondary malignant neoplasm of brain and cerebral meninges
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.4	Secondary malignant neoplasm of other and unspecified parts of nervous system
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.5	Secondary malignant neoplasm of bone and bone marrow
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.6	Secondary malignant neoplasm of ovary
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.7	Secondary malignant neoplasm of adrenal gland
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland

C79.72	Secondary malignant neoplasm of left adrenal gland
C79.8	Secondary malignant neoplasm of other specified sites
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site

Interleukin-2 or Other Central or Peripheral Vein Chemotherapy ICD-10-PCS Codes	
ICD-10-PCS	**Description**
3E03002	Introduction of high-dose interleukin-2 into peripheral vein, open approach
3E03003	Introduction of low-dose interleukin-2 into peripheral vein, open approach
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E03302	Introduction of high-dose interleukin-2 into peripheral vein, percutaneous approach
3E03303	Introduction of low-dose interleukin-2 into peripheral vein, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04002	Introduction of high-dose interleukin-2 into central vein, open approach
3E04003	Introduction of low-dose interleukin-2 into central vein, open approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E04302	Introduction of high-dose interleukin-2 into central vein, percutaneous approach
3E04303	Introduction of low-dose interleukin-2 into central vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

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The applicant used the FY 2019 MedPAR file dataset with the FY 2019 Final Rule with Correction Notice IPPS Impact File and the FY 2022 New Technology Thresholds to perform their cost analyses. Using the FY 2019 MedPAR file dataset, the applicant's search resulted in the identification of 20 MS–DRGs to which cases in the primary cohort mapped, as previously listed. The applicant provided two sensitivity cohorts: (1) A principal or admitting ICD–10 diagnosis of melanoma and metastasis; and (2) any ICD–10 diagnosis of melanoma and metastasis. The applicant stated that the analysis was limited to Medicare discharges from facilities paid under the IPPS by only including hospitals listed in the FY 2019 Final Rule IPPS Impact File. The previously discussed criteria resulted in 220 claims from 20 MS–DRGs in the primary cohort, 1,052 claims from 79 MS–DRGs in the sensitivity cohort 1, and 6,988 claims from 369 MS–DRGs in sensitivity cohort 2. The applicant imputed a case count of 11 for those MS–DRGs with fewer than 11 cases, which per the applicant resulted in a significantly higher case count than if it used the actual case counts. The applicant stated that imputing the cases did not change the results of the charge threshold analyses presented below, and the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold in all scenarios regardless of whether the actual case count or minimum case count of 11 is used. For each cohort, the applicant provided multiple analyses, by first using the threshold from each MS–DRG included, second using the MS–DRG 018 threshold for all included MS–DRGs and the national pharmacy CCR (0.187) to calculate charges, and lastly using the MS–DRG 018 threshold for all included MS–DRGs and the applicant-calculated CAR T-cell CCR (0.314) to calculate charges. For example, in the first analysis, the applicant used a threshold amount of $62,724 for MS–DRG 838 but in second and third analyses the applicant used a threshold of $1,251,126 for MS–DRG 838 (the same threshold for MS–DRG 018). The applicant first calculated a case weighted threshold of $70,220, $72,889, and $67,947 for the primary, sensitivity one, and sensitivity two cohorts respectively based on a case-weighted average of the threshold amounts for the MS–DRGs to which the cases identified based on the claims data search mapped. The applicant calculated a case weighted threshold of $1,251,126 for all secondary calculations where the MS–DRG 018 threshold was applied for all MS–DRGs identified. We note, in section II.D. of this proposed rule, we are proposing to assign other immunotherapies MS–DRG 018 (for example Introduction of lifileucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7), in addition to CAR T-cell therapies. Therefore, it seems the appropriate threshold for comparison is that of MS–DRG 018, with an average case-weighted threshold amount of $1,251,126.

For the analyses using the MS–DRG 018 thresholds, to calculate the average charge per case, the applicant used the cases identified based on the claims data search and mapped them to the MS–DRG 018 threshold. To determine the charges for lifileucel, the applicant converted cost to charges by dividing by the FY 2021 IPPS/LTCH PPS final rule national average pharmacy CCR of 0.187, and in secondary analyses, by a CAR T-cell CCR of 0.314 calculated by the applicant. To estimate the CAR T-cell CCR, the applicant obtained the MS–DRG 018 arithmetic mean charge in the AOR/BOR FY2021 Proposed Rule File released by CMS ($1,387,946). The applicant subtracted publicly reported non-drug charges for TECARTUS of $201,610 from the total arithmetic mean charge to estimate CAR T-cell charges (approximately $1,186,336). The applicant then divided a CAR T-cell wholesale acquisition cost of $373,000 (WAC for those CAR T-cell products approved as of FY 2019) by the estimated CAR T-cell charges, to estimate a CAR T-cell CCR of 0.314 (CCR = 373,000/1,186,336).

The applicant stated no charges were removed for the prior technology because previous treatments will continue to be reflected in cases where

lifileucel is administered. Next the applicant calculated the average standardized charge per case using the FY 2019 IPPS/LTCH PPS final rule Impact file. The 2-year inflation factor of 13.2% (1.13218) was obtained from the FY 2021 IPPS/LTCH PPS final rule and applied to the average standardized charge per case.

The applicant calculated the final inflated average case-weighted standardized charge per case by adding the estimated charges for the technology to the inflated average standardized charge per case. The applicant determined a final inflated average case-weighted standardized charge per case of $2,188,043 and $1,355,334 from the primary cohort, pharmacy and CAR T-cell CCR analyses with CAR T-cell thresholds respectively, which both exceed the average case-weighted threshold amount of $1,251,126.

The applicant determined a final inflated average case-weighted standardized charge per case of $2,134,830 and $1,302,121 from the sensitivity cohort one using the pharmacy and CAR T-cell CCR analyses with CAR T-cell thresholds respectively, which both exceed the average case-weighted threshold amount of $1,251,126.

The applicant determined a final inflated average case-weighted standardized charge per case of $2,131,524 and $1,298,815 from the sensitivity cohort two using the pharmacy and CAR T-cell CCR analyses with CAR T-cell thresholds respectively, which both exceed the average case-weighted threshold amount of $1,251,126. Because the final inflated average case-weighted standardized charge per case for all the analyses exceeded the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

Based on the information provided by the applicant, we have the following concerns regarding the cost analysis.

As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR, we are uncertain how representative this data is for use in the applicant's cost analyses given this potential for variability.

The applicant also uses both ICD–10 diagnosis code categories and subcategories which are not valid diagnosis codes and therefore, not appropriate to include for purposes of the cost analysis. There is a potential that inappropriately including ICD–10 diagnosis code categories and subcategories may alter the number of cases identified for inclusion in the cost analysis. We are seeking public comment on whether this issue may affect the cost analysis.

We continue to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. We invite public comments on whether lifileucel meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that lifileucel represents a substantial clinical improvement over existing technologies. In support of this assertion, the applicant provided data from two cohorts of the C–144–01 study, an ongoing phase 2, multicenter study (NCT02360579) consisting of four cohorts:

- Cohort 1 (n=30 generation 1 non-cryopreserved TIL product), not included for review as part of the applicant's new technology add-on payment application.
- Cohort 2 (n=60 generation 2 cryopreserved TIL product), included for review as part of the applicant's new technology add-on payment application.
- Cohort 3 (a sub-sample of n=10 from cohorts 1, 2, and 4), not included for review as part of the applicant's new technology add-on payment application.
- Cohort 4 (n=75 generation 2 cryopreserved TIL product), included for review as part of the applicant's new technology add-on payment application and also provided to the FDA as part of the applicant's BLA application.

The applicant stated that C–144–01 (NCT02360579) is a multi-cohort, Phase 2 clinical trial evaluating the safety and efficacy of lifileucel in patients that have been diagnosed with unresectable or metastatic Stage IIIc or IV melanoma. In addition to what the applicant previously described, the authors stated that in a sub-group analysis of 42 patients who were primary refractory to anti-PD–1, the ORR was 40.5% comparable to the overall cohort.

According to the applicant, the primary objective of this study was to evaluate the efficacy of lifileucel in patients with unresectable or metastatic melanoma using the objective response rate (ORR), as assessed by the independent review committee (IRC) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.[353] The applicant added that secondary objectives were to: (1) Evaluate the efficacy endpoints of duration of response (DOR), disease control rate (DCR), and progression free survival (PFS); (2) further evaluate the efficacy of lifileucel in patients with unresectable or metatstatic melanoma by assessing ORR, DOR, DCR, and PFS; (3) to evaluate overall survival (OS); and (4) to characterize the safety profile of lifileucel. For cohort 2, 60 patients were determined to allow estimation of the ORR using the maximum half width of the two-sided 95% confidence limit of less than 13.2% when ORR is expected to range from 20–50%. For cohort 4, approximately 75 patients were planned to be infused based on the null hypothesis of 10% ORR (based on historical control) which resulted in over 90% power to demonstrate superiority to this control. Patients included in this study were 18 years or older, had an ECOG (Eastern Cooperative Oncology Group) performance status of 0 or 1 upon entry, an estimated life expectancy of less than or equal to 3 months, and had unresectable or metastatic melanoma (stage IIIC or IV) treated with at least one prior systemic therapy including an anti-PD–1 antibody and a BRAF/MEK inhibitor. Patients were required to have a washout period of at least 28 days from prior anticancer therapy(ies) to the start of the planned nonmyeloablative lymphodeletion (NMA–LD) preconditioning regimen. The applicant explained that prior to the infusion of lifileucel, the patient receives NMA–LD with cyclophosphamide (60 mg/kg) intravenously daily for 2 days followed by fludarabine (25 mg/m^2) intravenously for 5 days to eliminate potentially suppressive immune cells which support the tumor and to maximize engraftment and potency of the lifileucel therapy through homeostatic proliferation.[354]

The applicant stated that the patients in this study had a high tumor burden at baseline and had received a mean of 3.3 lines (range, 1–9) of prior therapies. Twenty-eight patients (42%) had liver and/or brain lesions at baseline. Each prior line of therapy was defined as any

[353] Eisenhauer EA, et al. New response evaluation criteria in solid tumours: Revised RECIST guideline (version 1.1). European Journal of Cancer. 45 (2009) 228–247.

[354] Rosenberg, SA and Restifo, N. Adoptive cell transfer as personalized immunotherapy for human cancer, Science. 2015;348 (6230):62–68.

concomitant therapy given to the patient even if more than one target for each treatment was involved.[355] The applicant added that 77% of patients had progressed on prior anti-CTLA–4 blockade therapy, 99% had progressed on prior anti-PD–1/PD–L1 therapy, and 23% had received BRAF/MEK inhibitors. All patients had received PD on their prior therapy before study entry.

As justification for the null hypothesis of ORR less than or equal to 10%, the applicant stated that according to the NCCN guideline for metastatic melanoma, the only approved treatment is dacarbazine (DTIC) whereas other agents such as carboplatin, paclitaxel, docetaxel, nab-paclitaxel, and temozolomide are not approved by the FDA and are not appropriate as comparators. The applicant next presented the results from four studies which had at least one treatment arm receiving DTIC: (1) An abstract of a sample with metastatic melanoma previously treated with post-anti-PD–1 (no prior BRAF/MEK, metastatic melanoma) which resulted in a 10% ORR in the DTIC arm; [356] (2) a sample with advanced melanoma previously treated with post-ipilimumab (+/− BRAF inhibitor) which resulted in a 10.6% ORR in the DTIC arm, (3) a sample of treatment-naïve patients with unresectable stage IIIc or IV melanoma which resulted in a 9.8% ORR in the DTIC arm,[357] and (4) a sample of chemo-naïve patients with metastatic melanoma of which 9% had received prior therapy for metastatic disease which resulted in an 11% ORR in the DTIC arm.[358] The applicant stated that the historical control ORR of 10% for advanced melanoma was used for two reasons. First, the results from the first study (post-anti-PD–1) [359] most closely represent patients in the C–144–01 study because they received prior anti-PD–1 treatment while the other studies did not. Second, the applicant stated that response rates to chemotherapy, including DTIC, in recent phase 3 melanoma trials ranged from 4% to 10%.[360] [361] Also included in the application is a summary of results from six studies in patients treated with a DTIC monotherapy in advanced or metastatic melanoma prior to checkpoint inhibitor FDA approval which showed ORRs ranging from 5%–20%.

Next, the applicant discussed the efficacy results from the C–144–01 study. The applicant stated that regardless of location of tumor resected and BRAF mutational status, and across ages (20–79), patients responded to lifileucel therapy. Among patients in cohort 2 (n=66) there was an ORR of 36% (95% CI 25, 49) and a DCR of 80% (95% CI 69, 89). When considering best overall response, two patients (3%) achieved complete response (CR), 22 patients (33%) achieved partial response (PR), 29 patients (44%) achieved stable disease, 9 patients (14%) had progressive disease, and 4 patients (6%) were non-evaluable. The applicant highlighted that the ORR (36.5% for those less than 65 years and 35.7% for those 65 and older) and DCR (71.2% for those less than 65 years and 78.6% for those 65 and older) were consistent across age groups. The applicant contends that these results following the one-time, single infusion of lifileucel represent a substantial improvement over chemotherapy which offers poor ORR of 4%–10%.[362] [363]

Next, the applicant asserted that, because the median duration of response (DOR) had not been reached at a median follow-up of 18.7 months, the treatment effect will be durable and provide long-term benefit to those treated with lifileucel. The applicant stated that at the median follow-up, 50% (n=12) of responders showed ongoing response to lifileucel. The applicant added that the median DOR for treatment with DTIC is 5 to 6 months [364] [365] and that retreatment with an immune checkpoint inhibitor or chemotherapy has demonstrated a median overall survival of around 7–8 months.[366] [367]

Lastly, the applicant stated that the safety profile of lifileucel was consistent with the underlying advanced disease and the known toxicities associated with the single course of lymphodepleting preconditioning regimen and IL–2. The applicant stated that all patients experienced at least one treatment-emergent adverse event (TAEA) during the course of the study with the most common adverse event of any grade being hematologic along with chills, pyrexia, fatigue, tachycardia, and hypotension.[368] The applicant added that the most common grade ¾ TEAEs included thrombocytopenia (82%), anemia (56%), febrile neutropenia (55%), neutropenia (39%), hypophosphatemia (35%), leukopenia (35%), and lymphopenia (32%),[369] which were consistent with the lymphodepletion regimen and known profile of IL–2.[370] [371] [372] One patient died due to intra-abdominal hemorrhage reported as possibly related to TIL and one due to acute respiratory failure

[355] Ghate S, et al. Patterns of treatment and BRAF testing with immune checkpoint inhibitors and targeted therapy in patients with metastatic melanoma presumed to be BRAF positive. Melanoma Res 2019;29:301–10.

[356] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[357] Ribas A, et al. Phase III randomized clinical trial comparing tremelimumab with standard-of-care chemotherapy in patients with advanced melanoma. J Clin Oncol. 2013;31(5):616–622.

[358] Hersh EM, et al. A randomized, controlled phase III trial of nab-Paclitaxel versus dacarbazine in chemotherapynaive patients with metastatic melanoma. Ann Oncol. 2015;26(11):2267–2274.

[359] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588-e.

[360] NCCN Clinical Guidelines in Oncology (NCCN Guidelines. Cutaneous Melanoma. Versions 2018 and 2019. *https://www.nccn.org/professionals/physician_gls/#site.*

[361] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[362] Larkin J, et al. Overall survival in patients with advanced melanoma who received nivolumab versus investigator's Choice chemotherapy in CheckMate 037: a randomized, controlled, open-label Phase III trial. J Clin Oncol 2018;36:383–90.

[363] Ribas A, et al. Pembrolizumab versus investigator-choice chemotherapy for ipilimumab-refractory melanoma (KEYNOTE–002): A randomised, controlled, phase 2 trial. Lancet Oncol. 2015; 16(8): 908–18.

[364] Gogas HJ, et al. Chemotherapy for metastatic melanoma: Time for a change? Cancer 2007;109:455–64.

[365] Serrone L, et al. Dacarbazine-based chemotherapy for metastatic melanoma: Thirty-year experience overview. J Exp Clin Cancer Res 2000;19: 21–34.

[366] Kirchberger MC, et al. Combined low-dose ipilimumab and pembrolizumab after sequential ipilimumab and pembrolizumab failure in advanced melanoma. Eur J Cancer. 2016;65: 182–184. doi:10.1016/j.ejca. 2016.07.003.

[367] Goldinger SM, et al. The utility of chemotherapy after immunotherapy failure in metastatic melanoma: A multicenter case series. J Clin Oncol 2018;36:e21588–e.

[368] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[369] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[370] Rosenberg SA, et al. Durable complete responses in heavily pretreated patients with metastatic melanoma using Tcell transfer Immunotherapy. Clinical Cancer Research. 2011; 17(13):4550–4557. doi:10.1158/1078–0432.CCR–11–0116. 2,75,101

[371] Goff SL, et al. Randomized, prospective evaluation comparing intensity of lymphodepletion before adoptive transfer of tumor-infiltrating lymphocytes for patients with metastatic melanoma. J Clin Oncol. 2016 Jul 10;34(20):2389–97. PubMed PMID: 27217459. Pubmed Central PMCID:PMC4981979.

[372] Dudley ME, et al. Adoptive cell therapy for patients with metastatic melanoma: Evaluation of intensive myeloablative chemoradiation preparative regimens. J Clin Oncol. 2008; 26(32): 5233–5239.

assessed as not related to TIL.[373] The applicant stated that there was no difference in the incidence of TEAEs (for example any grade, among grades 3 to 4, and among grade 5) in patients 65 or older as compared to those younger than 65. Furthermore, the applicant stated that AEs occurred and generally resolved within the first 14 days following TIL infusion and IL–2 administration, during which time patients typically remained in the inpatient setting.

In support of its claims regarding substantial clinical improvement, the applicant submitted four additional pieces of evidence.[374] [375] [376] [377] First is an article which describes the tumor-infiltrating lymphocytes (TIL) manufacturing process, the mechanism of action of these products, what the authors identify as clear advantages of TIL in the treatment of solid tumors, and lastly the results of C–144–01.[378] The authors stated that this onetime autologous treatment involves a product individually derived for each patient, is not selected for the recognition of shared antigens that would be expressed in normal tissues, and is specific to the tumor neoantigens, reducing the risk for autoimmune toxicity. The authors also stated that the TIL mechanism of action does not rely on engineered receptors but maintains some physiologic control and avoids hyperactivation, which therefore suggests that TIL offers a different safety profile compared to CAR T-cell products or ICIs.

The second piece of evidence provided by the applicant is a presentation given at the 2020 ASCO annual meeting [379] which, per the applicant, focused on the C–144–01 study design, overview, patient procedures, TIL manufacturing, and patient characteristics of cohort 2. The presentation asserts, as the applicant has previously, that there are currently no approved agents for patients with metastatic melanoma whose disease progressed after ICIs and BRAF/MEK inhibitors. The presentation repeats study design, patient characteristics of cohort 2, safety outcomes, and efficacy outcomes, as previously described by the applicant. The presentation states that the adverse event profile was consistent with the underlying advanced disease and the safety profile of the lymphodepletion and IL–2 regimens and adds that the median number of IL–2 doses administered was six. The author concluded that lifileucel had demonstrated potential efficacy and durability of response for patients with metastatic melanoma and that it represented a viable therapeutic option warranting further investigation (that is, pivotal Cohort 4).

The applicant next submitted an abstract from a poster presentation [380] that discusses the TIL manufacturing process and the previously discussed study C–144–01. The presentation adds that tumors resected at local institutions were processed in central Good Manufacturing Practice (GMP) facilities for TIL production in a 22-day process. Final TIL infusion product was cryopreserved and shipped to sites. Patients received one week of cyclophosphamide/fludarabine preconditioning lymphodepletion, a single lifileucel infusion, followed by up to 6 doses of IL–2. The authors conclude by stating that response per IRC assessment and concordance between investigator read ORR and IRC will be reported.

Lastly, the applicant submitted a peer-reviewed and published post summary presented at the Society for Melanoma Research 2019 annual meeting [381] that discusses the results of the C–144–01 study as previously discussed by the applicant and other presentations. The author added that TIL therapy uses a patient's own immune cells to attack cancer. Tumor-infiltrating lymphocyte cells are extracted from a patient's own tumor tissue, expanded through a proprietary process, and infused back into the patient. After infusion, tumor-infiltrating lymphocytes reach tumor tissue, where they attack tumor cells. Lastly the author concluded that lifileucel treatment resulted in a 36.4% overall response rate with a median duration of response having not been reached after a median of one year in patients with heavily pretreated metastatic melanoma with high baseline disease burden who received prior anti-PD–1 and BRAF/MEK inhibitors.

After review of the information provided by the applicant, we have the following concerns concerning the substantial clinical improvement criterion. We note that results provided by the applicant are based on an ongoing phase two trial, C–144–01, and that these are potentially partial results from which we may not be able to draw end conclusions. We also note the potential for overestimating treatment effects when trials stop early or report interim results.[382] [383] [384]

We question the selection of ORR as the primary outcome, which combines the results of complete and partial responders. Specifically, we question if the results experienced by those who are complete responders may substantially differ from those who are partial responders. We also question the appropriateness of combining these two groups together. Further, we note that the applicant used a surrogate endpoint (ORR) rather than overall survival or other measure. We believe that this measure may not be the most appropriate measure with which to evaluate substantial clinical improvement in this patient population because it may not capture patients' clinical experience as fully as a measure of overall survival at some later time point. We are seeking public comment on whether the ORR is an appropriate measure of efficacy of this and other treatments when considering substantial clinical improvement.

[373] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[374] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

[375] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[376] Sarnaik A, et al. Safety and efficacy of lifileucel (LN–144) tumor infiltrating lymphocyte therapy in metastatic melanoma patients after progression on multiple therapies—independent review committee data update. Poster presented at SITC 2019. Poster Number: P865 and abstract; Journal: J Immunotherapy Cancer 2020;8:A12. Sarnaik, *et al.* SITC 2019

[377] Sarnaik A, et al. Lifileucel therapy leads to durable response in heavily pretreated, refractory, advanced melanoma. Poster presented at SMR 2019. Pending publication; online access: Advanced Melanoma, Practice Update, March 11, 2020.

[378] Fardis M, et al. Current and future directions for tumor infiltrating lymphocyte therapy for the treatment of solid tumors. Cell and Gene Therapy Insights, 2020; 6(6), 855–863.

[379] Sarnaik A, et al. Long-term follow up of lifileucel (LN–144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advance melanoma progressed on multiple prior therapies. Oral presentation at ASCO2020. Abstract Number: 10006; Journal: J Clin Oncol 38:2020.

[380] Sarnaik A, et al. Safety and efficacy of lifileucel (LN–144) tumor infiltrating lymphocyte therapy in metastatic melanoma patients after progression on multiple therapies—independent review committee data update. Poster presented at SITC 2019. Poster Number: P865 and abstract; Journal: J Immunotherapy Cancer 2020;8:A12.

[381] Sarnaik A, et al. Lifileucel therapy leads to durable response in heavily pretreated, refractory, advanced melanoma. Poster presented at SMR 2019. Pending publication; online access: Advanced Melanoma, Practice Update, March 11, 2020.

[382] Pocock SJ. When (not) to stop a clinical trial for benefit. JAMA 2005; 294:2228e30.

[383] Pocock SJ, Hughes MD. Practical problems in interim analyses, with particular regard to estimation. Control Clin Trials 1989; 10(4 Suppl): 209Se21S.

[384] Montori VM, Devereaux PJ, Adhikari NK, Burns KE, Eggert CH, Briel M, et al. Randomized trials stopped early for benefit: A systematic review. JAMA 2005; 294:2203e9.

Lastly, we note that a historical control is used for all of the studies provided and that the analyses using this historical control do not account for baseline differences between the groups being compared. This makes it difficult to determine if the results seen are due to the treatment, random occurrences, or bias. Further, we note that the patient sample or samples used to construct the historical control may not be representative of the C–144–01 cohort. We are unable to verify the appropriateness of this historical control because the evidence describing the historical control takes the form of abstracts or was not provided.

We are inviting public comments on whether lifileucel meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for lifileucel.

k. Narsoplimab

The Omeros Corporation submitted an application for new technology add-on payments for narsoplimab for FY 2022. Narsoplimab is a fully human monoclonal antibody for the treatment of HSCT–TMA, also known as transplant-associated thrombotic microangiopathy (TA–TMA), for which the applicant has submitted a Biologics License Application (BLA). According to the applicant, narsoplimab inhibits mannan-binding lectin serine protease 2 (MASP–2), the effector enzyme of the lectin pathway of the complement system, and activation of the lectin pathway that prevents complement-mediated inflammation and exhibits anticoagulant effects while leaving intact the respective functions of the classical and alternative pathways of innate immunity. According to the applicant, there are currently no FDA-approved products indicated for the treatment of hematopoietic stem cell transplantation-associated thrombotic microangiopathy (HSCT–TMA).

According to the applicant, HSCT–TMA is a lethal complication of hematopoietic stem cell transplantation (HSCT) that results in thrombosis in the small blood vessels, leading to organ failure.[385] [386] [387] According to the applicant, clinical guidelines for the treatment of HSCT–TMA are being developed by members of the American Society for Transplant and Cellular Therapy (ASTCT) and are expected to be published in 2021. The applicant stated that current management of HSCT–TMA includes modification or cessation of any immune-suppressive regimen, appropriate treatment of infections and/or graft-versus-host disease (GvHD) if present, aggressive control of hypertension, and other supportive therapy as deemed appropriate by the treating physician.[388] However, according to the applicant, the withdrawal of immunosuppressive therapies and ongoing monitoring for resolution of TMA symptoms has been determined to be ineffective.[389] The applicant stated that there are multiple off-label treatments for HSCT–TMA which have either not been reviewed by the FDA or have been reviewed and not deemed adequate for registration purposes; these unapproved treatments include therapeutic plasma exchange (TPE), eculizumab, defibrotide sodium, rituximab, and vincristine sulfate. The applicant asserted that available evidence for agents used off-label to treat HSCT–TMA is derived from observational studies and case series with mixed results, and none of the agents have been evaluated for efficacy or safety in a robust clinical trial in patients with HSCT–TMA.[390] In summary, the applicant stated with regard to these unapproved therapies that: (1) The use of TPE is based on the extrapolation of its effectiveness for thrombocytopenic purpura with poor outcomes leading the Blood and Marrow Transplant Clinical Trials Network Toxicity Committee in 2005 to recommend that TPE not be considered as a standard of care for HSCT–TMA; [391] (2) eculizumab is a C5 inhibitor that blocks activation of the terminal cascade of complement [392] of which the use is constrained by lack of efficacy and safety evaluations by the FDA [393] and associated increased susceptibility to infections; [394] [395] (3) defibrotide (Defitelio®), an oligonucleotide mixture with profibrinolytic properties whose mechanism of action has not been fully elucidated [396] is not approved by the FDA for the treatment of HSCT–TMA nor considered a standard of care; (4) rituximab (Rituxan®), a monoclonal antibody that targets the CD20 antigen expressed on the surface of pre-B and mature B-lymphocytes,[397] is not approved by the FDA for the treatment of HSCT–TMA; and (5) Vincristine sulfate, a vinca alkaloid isolated as a 1:1 sulfate salt from the periwinkle plant is not approved by the FDA for the treatment of HSCT–TMA.[398]

With respect to the newness criterion, the applicant stated in its application that it is in the process of completing a rolling submission of a Biologics License Application (BLA) to the FDA for narsoplimab for the treatment of HSCT–TMA. According to the applicant, narsoplimab has received Orphan Drug designation and Breakthrough Therapy Designation from FDA for the treatment of patients with HSCT–TMA who have persistent thrombotic microangiopathy despite modification of immunosuppressive therapy. The applicant submitted a request for approval for a unique ICD–10–CM code for HSCT–TMA and an

[385] Gavriilaki, E et al. Transplant-associated thrombotic microangiopathy: Opening Pandora's box. Bone Marrow Transplantation (2017) 52, 1355–1360.

[386] Jodele, S et al (2016). New approaches in the diagnosis, pathophysiology, and treatment of pediatric hematopoietic stem cell transplantation-associated thrombotic microangiopathy. Transfus Apher Sci. 2016 April; 54(2): 181–190.

[387] Rosenthal, J Hematopoietic cell transplantation-associated thrombotic microangiopathy: A review of pathophysiology, diagnosis, and treatment. Journal of Blood Medicine 2016:7 181–186.

[388] Khosla J et al. Hematopoietic stem cell transplant-associated thrombotic microangiopathy: Current paradigm and novel therapies. Bone Marrow Transplant. 2018; 53(2):129–137.

[389] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019; 25(3):570–576.

[390] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019; 25(3):570–576.

[391] Schwatz, J et al. Guidelines on the Use of Therapeutic Apheresis in Clinical Practice—Evidence-Based Approach from the Writing Committee of the American Society for Apheresis: The Seventh Special Issue. Journal of Clinical Apheresis 31:149–338 (2016).

[392] FDA. (2019, june). *Soliris Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125166s431lbl.pdf.*

[393] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019;25(3):570–576.

[394] Bohl SR, Kuchenbauer F, von Harsdorf S, Kloevekorn N, Schonsteiner SS, Rouhi A, et al. Thrombotic Microangiopathy after Allogeneic Stem Cell Transplantation: A Comparison of Eculizumab Therapy and Conventional Therapy. Biol Blood Marrow Transplant. 2017; 23(12):2172–7.

[395] Khosla J et al. Hematopoietic stem cell transplant-associated thrombotic microangiopathy: Current paradigm and novel therapies. Bone Marrow Transplant. 2018; 53(2):129–137.

[396] FDA. (2016, march). *Defitelio Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208114lbl.pdf* Defitelio PI. 3/2016.

[397] FDA. (2019, september). Rituxan *Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/103705s5450lbl.pdf* Rituxan PI. 9/2019.

[398] FDA. (2020, july). Vincristine *Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/202497s011lbl.pdf* Vincristine PI. 7/2020.

ICD–10–PCS code for the administration of narsoplimab; there are currently no ICD–10–CM codes that describe HSCT–TMA or ICD–10–PCS codes that describe narsoplimab.

If a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that narsoplimab has a unique mechanism of action as it is the first therapeutic to target mannan-binding lectin serine protease 2 (MASP–2) and the first to inhibit the lectin pathway of the complement system. The applicant stated that MASP–2 inhibition specifically blocks the lectin pathway of complement but does not inhibit the classical and alternative pathways, leaving the complement system's effector function in adaptive immunity intact, which is important for fighting infection.[399] [400] According to the applicant, the mechanism of action of narsoplimab not only results in inhibition of lectin pathway-mediated activation of complement, but also blocks the MASP–2 mediated procoagulant activities in the coagulation cascade. The procoagulant effects of MASP–2, independent of its role in the complement system, include the conversion of prothrombin to thrombin as well as the activation of Factor XII to XIIa.[401] [402] [403] In addition, MASP–2 is activated by fibrin and activated platelets, further augmenting a procoagulant state.[404] The applicant asserted that by inhibiting these procoagulant activities of MASP–2, narsoplimab provides important anticoagulant benefits, without affecting bleeding parameters (that is, prothrombin time, activated partial thromboplastin time, international normalized ratio, or bleeding time). According to the applicant, narsoplimab is the only drug that addresses all the components of HSCT–TMA and is the only product that inhibits complement activation and has anticoagulant activity. Therefore, the applicant asserts that the mechanism of action of narsoplimab differs from that of the products occasionally used off label: eculizumab, defibrotide sodium, rituximab, and vincristine.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant stated that patients who receive narsoplimab will be assigned to the same DRGs as patients who are diagnosed with HSCT–TMA/transplant-associated thrombotic microangiopathy (TA–TMA) regardless of the treatment.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that narsoplimab treats a different disease than existing technologies. According to the applicant, when treating HSCT–TMA, clinicians may rely on approaches that have limited efficacy [405] such as to reduce or discontinue anti-GVHD therapies (for example, calcineurin inhibitors), initiate therapeutic plasma exchange (TPE), and/or administer anti-CD20 antibody therapies, terminal complement inhibitors and/or oligonucleotide therapies.[406] [407] [408] The applicant stated that narsoplimab will be the first technology specifically indicated to treat HSCT–TMA.

According to the applicant, existing products that are currently used off-label to treat HSCT–TMA patients are indicated for the treatment of other distinct diseases. Eculizumab is indicated for: (1) The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis; (2) the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy; (3) the treatment of anti-acetylcholine antibody-positive generalized myasthenia gravis; and (4) the treatment of anti-aquaporin-4 (AQP4) antibody-positive neuromyelitis optica spectrum disorder (NMOSD).[409] Defibrotide sodium is indicated for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD) with renal or pulmonary dysfunction following HSCT.[410] The applicant further asserted that HSCT–TMA is different from aHUS due to varying underlying causes (that is, Shiga toxin infection, genetic mutation),[411] its association with receipt of a stem cell transplant and associated endothelial cell injury,[412] and aHUS resulting from mutations and/or polymorphisms in complement genes rather than having received an HSCT.[413] [414] In regard to VOD, the applicant asserts that while this patient population is similar to HSCT–TMA patients with regard to both having received HSCT, VOD is a separate disease affecting only the liver whereas HSCT–TMA is a multi-factorial disease impacting many organ systems, such as the kidneys, the lungs, the CNS and the gastrointestinal tract.[415]

Furthermore, the applicant summarized key distinctions between HSCT–TMA and the diseases for which

[399] Rambaldi, A et al. Improved survival following OMS721 treatment following hematopoietic stem cell transplant-associated thrombotic microangiopathy (HCTTMA). European Hematology Society. Stockholm, June 15, 2018. Abstract PF724.

[400] Elhadad, S et al 2020. MASP2 levels are elevated in thrombotic microangiopathies: association with microvascular endothelial cell injury and suppression by anti-MASP2 antibody narsoplimab. Clinical and Experimental Immunology, 0: 2–9.

[401] Demopulos, Gregory, A. Dudler, Thomas, Nilsson, Bo. Compositions and methods of inhibiting MASP–2 for the treatment of various thrombotic diseases and disorders. WO2019246367 (US20200140570A1). World International Property Organization. 26 December 2019.

[402] Krarup, A et al. Simultaneous Activation of Complement and Coagulation by MBLAssociated Serine Protease 2. 2007. PLoS ONE 2(7): e623.

[403] Gulla, KC et al. Activation of mannan-binding lectin-associated serine proteases leads to generation of a fibrin clot. Immunology, 2009. 129, 482–495.

[404] Kozarcanin, H et al. The lectin complement pathway serine proteases (MASPs) represent a possible crossroad between the coagulation and complement systems in thromboinflammation. Journal of Thrombosis and Haemostasis, 2016. 14: 531–545.

[405] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019; 25(3):570–576.

[406] Dhakal P et al. Is complement blockade an acceptable therapeutic strategy for hematopoietic cell transplant-associated thrombotic microangiopathy? Bone Marrow Transplant. 2017; 52(3):352–356.

[407] Khosla J et al. Hematopoietic stem cell transplant-associated thrombotic microangiopathy: current paradigm and novel therapies. Bone Marrow Transplant. 2018; 53(2):129–137.

[408] Li A et al. Transplant-associated thrombotic microangiopathy is a multifactorial disease unresponsive to immunosuppressant withdrawal. Biol Blood Marrow Transplant. 2019; 25(3):570–576.

[409] FDA. (2019, june). *Soliris Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/125166s431lbl.pdf* Soliris PI. 6/2019.

[410] FDA. (2016, march). *Defitelio Prescribing Information.* Retrieved from Highlights of Prescribing Information: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208114lbl.pdf* Defitelio PI. 3/2016.

[411] Lee, H et al. Consensus regarding diagnosis and management of atypical hemolytic uremic syndrome. 2020. Korean J Intern Med 2020; 35:25–40.

[412] Rosenthal, J Hematopoietic cell transplantation-associated thrombotic microangiopathy: a review of pathophysiology, diagnosis, and treatment. Journal of Blood Medicine 2016:7 181–186.

[413] Rosenthal, J Hematopoietic cell transplantation-associated thrombotic microangiopathy: a review of pathophysiology, diagnosis, and treatment. Journal of Blood Medicine 2016:7 181–186.

[414] Masias, C et al. None of the above: thrombotic microangiopathy beyond TTP and HUS. Blood. 2017; 129(21):2857–2863.

[415] Bonifazi, F et al. Diagnosis and Treatment of VOD/SOS After Allogeneic Hematopoietic Stem Cell Transplantation. Front Immunol. 2020; 11: 489.

the other off-label therapeutics are indicated (eculizumab, defibrotide sodium, plasmapheresis with fresh frozen plasma and rituximab). According to the applicant, HSCT–TMA is associated with HSCT endothelial cell injury, has unique triggers such as immune dysregulation caused by infection, chemotherapy, and GVHD, and involves the initiation of the complement system including the lectin pathway. Atypical hemolytic uremic syndrome (aHUS), treated by eculizumab, is associated with unchecked abnormal activation of alternative complement system due to genetic mutations in complement factors or inhibitory autoantibodies to factor H and I and has an onset that is idiopathic or secondary to triggers such as infection, fever, pregnancy, malignant hypertension, transplant, and diarrheal illnesses. Veno-occlusive disease (VOD), treated by defibrotide sodium, is a complication observed after HSCT where sinusoidal endothelial cells and hepatocytes in zone 3 of the hepatic acinus are damaged by toxic metabolites generated during the conditioning regimen. Thrombocytopenic purpura (TTP), treated by plasmapheresis with fresh frozen plasma and rituximab, is characterized by an ADAMTS–13 deficiency that is not commonly seen in HSCT–TMA with decreased ADAMTS activity due to genetic alterations to the gene or presence of inhibitory autoantibodies.

In summary, the applicant believes that narsoplimab is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. We note that the applicant asserts that there are no FDA-approved products indicated for the treatment of HSCT–TMA and we are inviting public comment on whether narsoplimab therefore has a unique mechanism of action. In addition, we note that although the cause or triggers of thrombotic microangiopathy may be different between HSCT and for example HUS or TTP, the resulting disease may be similar. We welcome public comments on whether HSCT–TMA is a similar disease to other forms of TMA.

We are inviting public comments on whether narsoplimab is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate the technology meets the cost criterion. The applicant stated that due to what it described as a lack of sufficient coding in the HSCT–TMA space, the applicant provided multiple scenarios to show that narsoplimab meets the cost criterion. The applicant stated they are not requesting that narsoplimab map to a new or different MS–DRG.

The applicant used the full calendar year 2019 National Medicare 100% inpatient Limited Dataset to identify patients with a combined diagnosis of history of stem cell transplantation (SCT, ICD–10 code Z94.84) OR complications of stem cell transplant (ICD–10 code T86.5) AND thrombotic microangiopathy (TMA, ICD–10 code M31.1) OR hemolytic-uremic syndrome (HUS, ICD–10 code D59.3). Claims from PPS-exempt hospitals were excluded. In the base case analysis where all MS–DRGs were included, a total of 83 cases across 38 MS–DRGs were identified. The applicant imputed a case count of 11 for those MS–DRGs with fewer than 11 cases, which increased the number of claims from 83 to 396 because all MS–DRGs had fewer than 11 claims. The applicant then varied this initial analysis in two ways. First, sensitivity analyses one and two varied the reduction for the charges related to the prior technology to 25 percent and 50 percent of prior related therapy charges, respectively, which are possibly tied to decreased length of stay and/or decreased ICU utilization. Second, the applicant provided four scenarios which varied the price of narsoplimab from zero to three greater values.

The applicant first calculated a case weighted threshold of $96,810 for all scenarios based upon the dollar threshold for each MS–DRG grouping and the proportion of cases in each MS–DRG. The applicant then calculated the average charge per case. The applicant stated that because narsoplimab is an adjunctive therapy, no charges for a prior technology or a technology being replaced were removed. In the base case analysis, no charges related to the prior technology were removed because narsoplimab is not anticipated to offset standard of care costs. However, according to the applicant, because of a reduction in complications leading to mortality and other clinically significant complications, narsoplimab is anticipated to decrease the rate of hospitalization and length of stay. Therefore, two sensitivity analyses were included which removed 25 percent and 50 percent of prior related therapy charges which could potentially be related to a decrease in length of stay and/or decrease in ICU utilization in sensitivity analyses one and two, respectively. The applicant stated the 50% charge reduction analysis was performed as an extreme analysis to examine the unlikely possibility that narsoplimab offsets a considerable amount of costs associated with treating TMA. Because of the reduction in complications leading to mortality and other clinically significant complications, the applicant asserted that for many with long-term sequelae, narsoplimab is anticipated to decrease the rate of hospitalization and length of stay. Next the applicant calculated the average standardized charge per case using the FY 2021 IPPS/LTCH PPS final rule Impact file. The 2-year inflation factor of 13.2% (1.13218) was obtained from the FY 2021 IPPS/LTCH PPS final rule and applied to the average standardized charge per case.

To determine the charges for narsoplimab, the applicant converted cost to charges by dividing by the FY 2021 IPPS/LTCH PPS final rule national average drug CCR of 0.187. No charges related to the use of the technology were added by the applicant because utilization of narsoplimab is not anticipated to result in incremental costs. The applicant calculated the final inflated average case-weighted standardized charge per case by adding the charges for the technology to the inflated average standardized charge per case. In the base analysis where a technology related price of $0 was used, the applicant determined a final inflated average case-weighted standardized charge per case of $363,815, which exceeds the average case-weighted threshold amount of $96,810. In the same base analysis, the applicant determined a final inflated average case-weighted standardized charge per case of $272,861 in scenario one of the sensitivity analyses, which exceeds the average case-weighted threshold amount of $96,810. Lastly, in the same base analysis, the applicant determined a final inflated average case-weighted standardized charge per case of $181,908 in scenario two of the sensitivity analyses, which exceeds the average case-weighted threshold amount of $96,810. The applicant then provided a secondary cost analysis where the price of narsoplimab was the average of the three greater values used as the charges for the technology, and identified a final inflated average case-weighted standardized charge per case of $898,574, $807,621, and $716,667 in the base, 25 percent sensitivity, and 50 percent sensitivity analyses respectively.

We note that in its application, the applicant only provided, in Excel format, the primary base analysis without sensitivity scenarios. We are therefore unable to verify all other analyses, to include the sensitivity

analyses, discussed in this section and in the application. The applicant includes many MS–DRGs which are defined by other factors which may or may not be related to the intended indication for narsoplimab. For instance, the applicant identified MS–DRG 193 (Simple Pneumonia and Pleurisy with MCC) for inclusion in the cost analysis. Therefore, we are uncertain if the cases identified in the preceding cost analysis adequately identify potential cases eligible for narsoplimab. We are seeking public comment with regard to whether the MS–DRGs used in these cost analyses are appropriately representative of the cases that would be eligible for use of the technology. We invite public comments on whether narsoplimab meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that narsoplimab represents a substantial clinical improvement over existing technologies. According to the applicant, compared to the current recommendation of cessation of immunosuppressive therapies, narsoplimab demonstrates a substantial clinical improvement for the treatment of HSCT–TMA because it fulfills an unmet need for patients, demonstrated a statistically significant complete response rate in the pivotal clinical trial, provides a reduction in clinically significant adverse events, resulted in higher 100-day survival rates, decreases the rate of subsequent therapeutic interventions, and is anticipated to decrease the rate of hospitalizations and length of stay.

The applicant asserts that narsoplimab offers a treatment option for a patient population unresponsive to current available treatments. According to the applicant, the FDA awarded narsoplimab Breakthrough Therapy designation after reviewing literature for patients similar to those in the applicant's pivotal trial. The applicant states that if approved by the FDA, narsoplimab will be the only drug or biological approved for the treatment of HSCT–TMA.

In support of the assertion that narsoplimab offers a treatment option for patients unresponsive to currently available treatments, the applicant provided an abstract of their pivotal trial, a single-arm trial of 28 adult HSCT–TMA patients.[416] The abstract states that patients who had not responded to immunosuppression modification and who had thrombocytopenia, evidence of microangiopathic hemolytic anemia, and increased creatinine were included in the study. The applicant adds that patients with mild disease were excluded from the study. Patients received narsoplimab intravenously once weekly for four or eight weeks with a 6-week follow up period. The primary endpoint was a response-based composite measure requiring improvement both in laboratory TMA markers (platelet count and Lactate Dehydrogenase (LDH)) and in clinical status (that is organ function). Secondary endpoints were surivival and changes in laboratory TMA markers. The applicant asserts that a complete response rate of 15% was identified in conjunction with the FDA as the threshold to demonstrate efficacy for narsoplimab. The applicant states that narsoplimab resulted in a 61% complete response rate (CRR) in patients with HSCT–TMA who received at least one dose of the drug; the per protocol analysis (that is, patients who received at least the per-protocol-specified 4 weeks of treatment) resulted in a 74% complete response rate. The applicant states that these complete response rates are higher than the expected response of 10% to 15% in the absence of narsoplimab.

In applying for Breakthrough Therapy designation, the applicant states that a literature review was conducted to identify studies in a patient population similar to that in the pivotal trial. Searching in PubMed using pre-identified search terms (transplant-associated thrombotic microangiopathy; thrombotic microangiopathy stem cell; and cancer-associated thrombotic microangiopathy), the applicant identified nine references that met inclusion criteria and excluded an unknown number of articles because the patient data was not included in the publication. Studies were included if they were published in the year 2000 or later and included: (1) Survival data for patients; (2) documentation that immunosuppression was modified; and (3) documentation of patient response to immunosuppression modification.[417]

Of the nine studies included, there was a mean sample size of 7.4 ranging from 1–17 totaling 67 participants. The applicant identified a median overall survival of 21 days (95% CI 15–29) which ranged from 7 to 43 days. The applicant compared these results to those of the pivotal trial, where 16 of 28 patients died with a median overall survival of 274 days ($p < 0.0001$) compared via a log-rank test to that identified in the literature review. The applicant stated that a one-hundred-day survival post HSCT–TMA diagnosis was observed in 68% (n=28) of the full analysis set, 83% (n=23) in the patients treated per the protocol, and 94% (n=17) of complete responders.

The applicant asserted that in a high-risk study population, narsoplimab demonstrated substantial clinical improvement compared to current treatment approaches, meaningfully decreasing the rates of clinically significant complications, including mortality, and reducing the need for subsequent interventions; as a result, narsoplimab is anticipated to decrease the rate of hospitalization and length of stay. The applicant stated that the primary objectives in the pivotal study for narsoplimab were to evaluate safety, tolerability, and response-based efficacy requiring improvement in TMA laboratory markers of platelet count and LDH and improvement in clinical status on the basis of transfusions, renal, pulmonary, gastrointestinal, and neurological symptoms. The applicant stated that platelet count on average increased from baseline over time, LDH decreased from baseline, haptoglobin steadily increased from baseline, and hemoglobin increased over time with the use of narsoplimab. The applicant reported that overall 48% and 55% of patients had freedom from red blood cell and platelet transfusions, respectively. The applicant asserted that due to the decreased rate of complications, narsoplimab has the potential to lead to decreased hospital length of stay as well as decreased intensive care usage.

Lastly, the applicant asserted that narsoplimab is well tolerated with no treatment related complications. The applicant stated that the most common adverse events in the pivotal trial were nausea, vomiting, diarrhea, hypokalemia, neutropenia, and fever, which are comparable to those typically seen in the post-transplant population. Six deaths (21%) occurred, collectively, from sepsis, AML progression, and graft-versus host disease, which according to the applicant are causes of death common in patients with HSCT.

In addition to the previously discussed pivotal trial abstract, the applicant submitted four additional citations (three case studies and one case series) in support of the substantial clinical improvement of narsoplimab. The first citation is described by the

[416] Rambaldi, A et al. Narsoplimab for the treatment of Adult Hematopoietic Stem Cell Transplant-Associated Thrombotic Microangiopathy European Hematology Society. Abstract S262. 2020.

[417] Rambaldi, A et al. Improved survival following OMS721 treatment following hematopoietic stem cell transplant-associated thrombotic microangiopathy (HCTTMA). European Hematology Society. Stockholm, June 15, 2018. Abstract PF724.

applicant as a case study of an 18-year-old patient with biopsy-proven HSCT–TMA of the gastrointestinal tract which required transfusions. The applicant states that the patient received narsoplimab which led to the resolution of TMA and all transfusions were discontinued. The applicant submitted an educational agenda in support of this citation which does not provide any additional information.[418]

The second citation concerns the results of a case study of a 14 year-old patient who did not tolerate eculizumab for the treatment of HSCT–TMA and was treated successfully with OMS721 (*i.e.,* narsoplimab). The applicant submitted the abstract which states that after receiving allogeneic HSCT, the patient began to show progressive deterioration.[419] The patient was treated twice with eculizumab at months seven and eleven both resulting in pulmonary edema. The patient next received narsoplimab after which he began to improve and did not experience any adverse events.

The third citation is a presentation given at the European Society for Blood and Marrow Transplantation in 2017 [420] which discusses a 46-year-old patient with T-acute lymphoblastic leukemia who received HSCT. The applicant states this case study is about a patient with HSCT–TMA and late-onset acute GI GVHD who was treated with narsoplimab which resulted in the resolution of melena and hemolysis, increased platelets, and neurologic improvements over 354 days.

Lastly, the applicant submitted a presentation which discusses the results of a case series.[421] The applicant states that laboratory marker and clinical improvement were seen following narsoplimab treatment in severely ill, complex patients with HSCT–TMA. The case series included results from 2 patients (age 19 and age 48), both of whom underwent HSCT, the latter of which was HIV positive. The 19-year-old patient received 18 doses of narsoplimab showing favorable response with resolution of gastrointestinal bleeding and microangiopathic hemolytic anemia. The 48-year-old patient received eight doses of narsoplimab, but despite partial improvement remained on transfusions and dialysis until sudden death on day 31.

After review of the provided information and citations we have concerns with regard to the substantial clinical improvement criterion. Firstly, the sample from which the applicant draws conclusions is small (sample size of pivotal trial 28, plus five case studies). Furthermore, we are unable to verify the methods, results, and conclusions of these studies as the applicant only provided evidence in the form of abstracts and presentations. For example, one citation provided by the applicant in the form of a non-peer-reviewed conference poster details interim results from what appear to be the pivotal trial.

With regard to methodological concerns, first, we note the potential for overestimating treatment effects when trials stop early or report interim results.[422] [423] [424] Second, the authors pool data from an historical cohort of patients drawn from published literature to calculate survival rates in patients with HSCT–TMA and then retrospectively compare these rates to the survival in their treated cohort. We are unable to evaluate the appropriateness of this historical comparison cohort based on the evidence provided in the form of two citations, an abstract [425] and a poster.[426] This analysis may not adequately account for baseline differences between the patients treated with narsoplimab and the patients across the articles from which a historical control was developed. In addition, we note that we may lack the ability to evaluate whether this literature review to obtain the historical control effectively identified the historical control, as the applicant only provided general details on how the search was performed.

We further note that the study design described in the pivotal trial, upon which the applicant bases its claims for substantial clinical improvement, was not appropriately designed to test for comparisons with another treatment such as an historical control. Furthermore, the methods utilized in the pivotal trial do not lend themselves to making statistical inferences based on the provided protocol (for example, no power assessment performed, no assessment for multiple comparisons, no pre-identified alpha).

We are inviting public comments on whether narsoplimab meets the substantial clinical improvement criterion.

We received one written comment in response to the New Technology Town Hall meeting notice published in the **Federal Register**. The commenter stated that they are enthusiastic about the results of the single arm open-label trial OMS721–TMA–001 evaluating narsoplimab for the treatment of HSCT–TMA. The commenter added that narsoplimab offers a treatment option for these high-risk patients that appears to markedly increase complete response rates with a substantial reduction in clinically significant complications including mortality. The commenter stated that the approval of the application for new technology add-on payments will help ensure appropriate patients will get the benefit of narsoplimab for treatment of HSCT–TMA.

Response: We appreciate the commenter's input and will take this comment into consideration when deciding whether to approve new technology add-on payments for narsoplimab for FY 2022.

l. NexoBrid™

Vericel Corporation submitted an application for NexoBrid™ for new technology add-on payments for FY 2022. According to the applicant, NexoBrid™ is a novel, non-surgical option for eschar removal (debridement). Eschar is the dead tissue and dried secretions from a skin wound following a burn, and removal is essential for wound healing. According to the applicant, NexoBrid™ is a mixture of proteolytic enzymes (enriched in bromelain) and has been developed for patients with deep partial thickness (DPT) and/or full thickness

[418] Rafael Duarte, Diagnosis and treatment options for transplant-associated microangiopathy. European Society for Blood and Marrow Transplantation (EBMT). Abstract 2019.

[419] Zecca, et al. Resolution of acute kidney injury secondary to HSCT–TMA by the anti-MASP–2 monoclonal antibody OMS721 in pediatric HSCT recipient. European Society for Blood and Marrow Transplantation (EBMT). Abstract 2017.

[420] Caprioli, et al. Effective treatment of GVHD-associated transplant-associated microangiopathy Transplant Complications Working Party. Crash course on diagnosis and treatment of non-infectious complications after HCT. 19–20 October 2017 in Granada, Spain in conjunction with the European Society for Blood and Marrow Transplantation (EBMT). Abstract 2017.

[421] Duarte, et al. Treatment of severe hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT–TMA) with the MASP–2 inhibitor narsoplimab (OMS721). European Society for Blood and Marrow Transplantation (EBMT). Abstract 2020.

[422] Pocock SJ. When (not) to stop a clinical trial for benefit. JAMA 2005; 294:2228e30.

[423] Pocock SJ, Hughes MD. Practical problems in interim analyses, with particular regard to estimation. Control Clin Trials 1989; 10(4 Suppl): 209Se21S.

[424] Montori VM, Devereaux PJ, Adhikari NK, Burns KE, Eggert CH,Briel M, et al. Randomized trials stopped early for benefit: a systematic review. JAMA 2005; 294:2203e9.

[425] Rambaldi, A et al. Improved survival following OMS721 treatment following hematopoietic stem cell transplant-associated thrombotic microangiopathy (HCTTMA). European Hematology Society. Stockholm, June 15, 2018. Abstract PF724.

[426] Rambaldi, A et al. Improved survival following oms721 treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (hct-tma). European Hematology Association (poster). Stockholm, June 15, 2018. Abstract PF724.

(FT) thermal burns. According to the applicant, NexoBrid™ has not yet received approval from FDA. The applicant further noted that NexoBrid™ was approved by the European Medicines Agency (EMA) in 2012 and is currently commercially available in many countries.

The applicant stated that timely, rapid debridement of eschar in burn patients is necessary for assessing the burn injury, initiating the wound healing process, and preventing further complications, such as local infection, sepsis and extension of the burn injury.[427] [428] [429] The applicant stated that NexoBrid™ has been identified by the Biomedical Advanced Research and Development Authority (BARDA) as a critical medical countermeasure to address the public health emergency need for a debridement product for the treatment of burns in adults, especially for mass casualty events, where surgical capacity is limited, and rapid assessment of burn severity and intervention are imperative.[430]

The applicant stated that the current standard of care for burn debridement includes surgical and non-surgical approaches. The applicant stated that the surgical approach relies primarily on surgical tangential excision through use of sharp instruments such as scalpels and dermatomes.[431] [432] The applicant stated that surgical procedures include minor excision, avulsion, hydrosurgery (for example, VERSAJET™), scraping, brushing, dermabrasion, and excisions.[433] The applicant stated that non-surgical standard of care treatments include enzymatic debridement such as clostridial collagenase ointment (example, SANTYL®), antimicrobial agents such as silver sulfadiazine (example, SILVADENE®), or various hydrogels.[434] [435] [436] [437] [438] [439]

According to the applicant, NexoBrid™ is a botanical and biologic product for topical use and is comprised of two components: The NexoBrid™ powder that contains the active pharmaceutical ingredient (API) and a Gel Vehicle. The NexoBrid™ API is a concentrate of proteolytic enzymes enriched in bromelain extracted from pineapple stems. The applicant stated that the mechanism of action of NexoBrid™ is mediated by the proteolytic activity of its enzymes and is associated with selective debridement of eschar and denatured collagen while sparing healthy tissue.

The applicant stated that according to the American Hospital Association (AHA) Coding Clinic, ''Non-excisional debridement is coded with root operation 'extraction' ''.[440] The applicant added that NexoBrid™ could be identified with ICD–10–PCS code series 0HD Extraction of Skin or 0JD Extraction of subcutaneous tissue and fascia. The applicant stated that it has not requested that its technology map to a new or different MS–DRG.

With respect to the newness criterion, the applicant stated they have not yet received FDA approval. The applicant submitted a Biologic License Application (BLA) for NexoBrid™ for FDA approval on June 30, 2020 on the basis of two pivotal Phase 3 clinical trials. In September 2020, the FDA accepted the application and communicated a PDUFA date of June 29, 2021.

The applicant indicated that the ICD–10–PCS code series for non-excisional debridement, 0HD (Extraction of Skin) or 0JD (Extraction of subcutaneous tissue and fascia) could be used to identify NexoBrid™ use. The applicant indicated that NexoBrid™ is not separately identified with a unique ICD–10–PCS code. The applicant submitted a request for an ICD–10–PCS code to uniquely identify the use of NexoBrid™ beginning in FY 2022.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would, therefore, not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant stated that NexoBrid™ is unique due to the bromelain active ingredient, which is extracted from pineapple stems. The applicant claimed that a search of the FDA website for the key words ''bromelain'' and ''pineapple'' did not yield any approved applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic (FD&C Act) or section 351(a) of the Public Health Service (PHS) Act.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant did not address the question directly, but stated that no existing technology used now or previously is similar to NexoBrid™ that would be captured under burn MS–DRGs as identified in the following table.

Current MS-DRG for Burns	MS-DRG Description
003	ECMO or Tracheostomy w MV >96 Hours or Principal Diagnosis Except Face, Mouth, and Neck w Major O.R. Procedures.
927	Extensive Burns or Full Thickness Burns w MV >96 Hours w Skin Graft.
928	Full Thickness Burn w Skin Graft or Inhalation Injury w CC/MCC.
929	Full Thickness Burn w Skin Graft or Inhalation Injury w/o CC/MCC.
934	Full Thickness Burn w/o Skin Graft or Inhalation Injury.
935	Non-Extensive Burns.

[427] Edmondson, S. J., Jumabhoy, I. A., & Murray, A. (2018). Time to start putting down the knife: A systematic review of burns excision tools of randomised and non-randomised trials. *Burns, 44*(7), 1721–1737.

[428] Gibran, N. S., et al. (2013). Summary of the 2012 ABA burn quality consensus conference. *Journal of Burn Care & Research, 34*(4), 361–385.

[429] Xiao-Wu, et al. (2002). Effects of delayed wound excision and grafting in severely burned children. *Archives of surgery, 137*(9), 1049–1054.

[430] BARDA Initiates the Procurement of NexoBrid for Emergency Response. *http://ir.mediwound.com/newsreleases/news-release-details/barda-initiates-procurement-nexobrid-emergency-response.*

[431] Edmondson, S. J., et al. (2018). Time to start putting down the knife: A systematic review of burns excision tools of randomised and non-randomised trials. *Burns, 44*(7), 1721–1737.

[432] Hindocha, S., et al. (2013). Burn eschar debridement: a review. *J. Wound. Technol.* July, 12–14.

[433] Legemate, C. M., et al. ''Application of hydrosurgery for burn wound debridement: an 8-year cohort analysis.'' *Burns* 45.1 (2019): 88–96.

[434] Loo, Y. L., Goh, B. K., & Jeffery, S. (2018). An overview of the use of bromelain-based enzymatic debridement (NexoBrid®) in deep partial and full thickness burns: appraising the evidence. *Journal of Burn Care & Research, 39*(6), 932–938.

[435] Pham, C. H., et al. (2019). The role of collagenase ointment in acute burns: a systematic review and meta-analysis. *Journal of wound care, 28*(Sup2), S9–S15.

[436] Cancio, L. C., Barillo, D. J., Kearns, R. D., Holmes IV, J. H., Conlon, K. M., Matherly, A. F., . . . & Palmieri, T. (2017). Guidelines for burn care under austere conditions: surgical and nonsurgical wound management. *Journal of Burn Care & Research, 38*(4), 203–214.

[437] Hansbrough, J. F., et al (1995). Wound healing in partial-thickness burn wounds treated with collagenase ointment versus silver sulfadiazine cream. *The Journal of burn care & rehabilitation, 16*(suppl_3_pt_1), 241–247.,

[438] Klasen, H. J. (2000). A historical review of the use of silver in the treatment of burns. II. Renewed interest for silver. *Burns, 26*(2), 131–138.,

[439] Soroff, H. S., & Sasvary, D. H. (1994). Collagenase ointment and polymyxin B sulfate/bacitracin spray versus silver sulfadiazine cream in partial-thickness burns: A pilot study. *The Journal of burn care & rehabilitation, 15*(1), 13–17.

[440] American Hospital Association (AHA) Coding Clinic, Volume 2, number 1, 2015, pg 23

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease, and the same or similar patient population when compared to an existing technology, the applicant stated that NexoBrid™ does treat the same patient population as existing approaches to eschar removal. The applicant further stated that the ability to use NexoBrid™ at the bedside offers an effective option for rapid eschar removal that avoids the operating room, and that the ability to use NexoBrid™ in delicate areas offers particular value in burn treatment.

We have the following concerns regarding whether the technology meets the substantial similarity criteria and whether it should be considered new. While the applicant discussed the differences between NexoBrid™ and products made by other manufacturers, we note the applicant does not provide enough information regarding the composition of the proteolytic enzymes used within the NexoBrid™ active pharmaceutical ingredient, its mechanism of action, and how the ingredient(s) differs from other enzymatic debridement products on the market. Specifically, it is not clear whether the proteolytic enzyme is a type of collagenase similar to existing collagenase based enzymatic debridement products, since the applicant claimed that NexoBrid™ debrides denatured collagen in the wound. In addition, the applicant states that NexoBrid™ uses a new ingredient but does not explain how this represents a new mechanism of action. We also note that, while the applicant did not state so directly, we believe that patients treated using NexoBrid™ would be assigned to the same MS–DRGs as those patients who were treated with competitive products or services used for burns. We further note that the applicant did not suggest that NexoBrid™ was used to treat a different population from existing treatments.

We are inviting public comments on whether NexoBrid™ is substantially similar to other currently available therapies and/or technologies, and whether NexoBrid™ meets the newness criterion.

With regard to the cost criterion, the applicant provided two scenarios: Scenario 1: without grafting, which excluded cases with an ICD–10–PCS code for replacement of skin, and Scenario 2: with grafting, which required at least one ICD–10–PCS code for replacement of skin. Under the first scenario, the applicant searched the FY 2019 MedPAR dataset for cases reporting ICD–10–CM diagnosis codes for second- or third-degree burns as a primary diagnosis, and an ICD–10–PCS code(s) for excision or extraction of skin or subcutaneous tissue and fascia; these criteria resulted in the identification of 347 cases mapping to three unique MS–DRGs. Under the second scenario, the applicant again searched the FY 2019 MedPAR dataset for the same ICD–10 codes but with an additional ICD–10–PCS code for replacement of skin. Under the second scenario, the applicant identified 1,283 cases mapping to five unique MS–DRGs. In the following tables the applicant lists the MS–DRGs to which cases are assigned in each scenario:

Scenario 1 Burn with Excision or Extraction without Grafting	
MS-DRG	**Description**
935	Non-Extensive Burns
934	Full Thickness Burn w/o Skin Graft or Inhalation Injury
928	Full Thickness Burn w Skin Graft or Inhalation Injury w CC/MCC

Scenario 2 Burn with Excision or Extraction and Grafting	
MS-DRG	**Description**
928	Full Thickness Burn w Skin Graft or Inhalation Injury w CC/MCC
929	Full Thickness Burn w Skin Graft or Inhalation Injury w/o CC/MCC
935	Non-Extensive Burns
927	Extensive Burns or Full Thickness Burns w MV >96 Hours w Skin Graft
003	ECMO or Tracheostomy w MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck w Major O.R. Procedures

With respect to the MS–DRGs identified based on the claims search and included in the cost analysis, particularly MS–DRG 003, the applicant confirmed that this MS–DRG was appropriately representative of potential NexoBrid™ patients.

The applicant used the FY 2019 MedPAR LDS file with the FY 2022 New Technology thresholds to calculate the case-weighted thresholds, and the FY 2019 FR IPPS/LTCH PPS standardizing file to standardize charges. The applicant then removed 100 percent of the operating room charges and 24.5 percent of the blood charges from the identified cases to conservatively estimate the charges that potentially may be avoided through the use of NexoBrid™. After standardizing the charges, the applicant applied what it indicated was the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges of 13.1 percent. We note that the inflation factor was 13.2 percent (1.13218) for FY 2021 (85 FR 59039), which would have resulted in higher inflated charges. To calculate the charges for the technology, the applicant divided the cost of the technology by the national average CCR for the Drugs cost center of 0.187 from the FY 2021 IPPS/LTCH PPS final rule.

Under scenario one, the applicant calculated a final inflated case-weighted average standardized charge per case of $95,828, which exceeded the average case-weighted threshold amount of $55,536. Under scenario two, the final inflated average case-weighted standardized charge per case of $334,405 exceeded the average case-weighted threshold amount of $168,985. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for both scenarios, the technology meets the cost criterion.

According to the applicant, NexoBrid™ is indicated for the treatment of thermal burns. The cost analysis performed by the applicant includes MS–DRG 003 (ECMO or Tracheostomy w MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck w Major O.R. Procedures), which per the applicant is appropriately representative of potential NexoBrid™ patients. However, MS–DRG 003 does not appear to be representative of the target patient population for NexoBrid™. We are seeking public comment on whether the use of this MS–DRG and others for the cost analysis appropriately reflects the potential cases treated by the technology.

We are inviting public comment on whether NexoBrid® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that NexoBrid™ can be used in a patient population that is unresponsive to, or ineligible for currently available treatments because NexoBrid™ can be used at the bedside and is therefore an effective eschar removal option for patients for whom surgery or general anesthesia may be contraindicated. The applicant asserted that NexoBrid™ allows for the diagnosis of a medical condition in a manner different from existing technology because it allows for depth-of-burn diagnoses of indeterminant depth and/or mixed depth wounds. The applicant also asserted that NexoBrid™ represents a substantial clinical improvement due to significantly improved clinical outcomes in the following ways: (1) Reduction in clinically significant adverse events by reducing the surgical burden associated with surgical excision, reducing donor site morbidity due to reduced autografting, reducing blood loss due to adoption of a non-surgical approach, and reduced usage of surgical escharotomies; (2) decreased rate in a subsequent diagnostic or therapeutic intervention by reducing the need for surgical excision and reducing the need for autografts; (3) improved quality of life due to reduced scarring associated with reduction in autografting; and (4) NexoBrid™ is aligned with key benefits to elderly burn patients who may be too unwell for surgical excision.

The applicant asserted that because NexoBrid™ can be used at the bedside, it provides a unique non-surgical option for rapid, consistent eschar removal in patients for whom surgery or general anesthesia may be contraindicated. The applicant claimed that currently available non-surgical eschar removal procedures are generally considered inefficient, can result in a lengthy sloughing period, and have the potential for development of granulation tissue and increased infection and scarring.[441] [442] [443]

The applicant submitted two pivotal Phase 3 clinical trials to primarily support its claims of substantial clinical improvement. The DETECT study (NCT02148705) is a multi-center, multi-national, assessor blinded, randomized, 3:3:1 controlled, three-arm study from which data is not yet publicly available. Per the applicant, this study aimed to demonstrate superiority of NexoBrid™ treatment over Gel Vehicle (placebo) control and standard of care treatment, in hospitalized adult subjects with DPT and/or FT thermal burn of 3–30% total body surface area (TBSA) and total burn wounds of no more than 30% TBSA. A total of 175 subjects were randomized in to the DETECT study with 169 subjects being treated with NexoBrid, SOC consisting of surgical and/or nonsurgical treatment as per the investigators' discretion, or placebo.[444] NCT00324311 is an earlier multi-center, open-label, randomized, controlled clinical trial including 156 patients aged 4–55 years with deep partial and full thickness burns covering 5–30% TBSA. Patients were randomly assigned to burn debridement with NexoBrid™ or standard of care, which included surgical excisional or non-surgical debridement.[445]

The applicant asserted that in patients with indeterminant partial-thickness and/or mixed depth burns, NexoBrid™ debridement allows for a more accurate assessment of burn depth. The applicant stated, ''each additional non-autografted NexoBrid™-treated patient (relative to standard of care eschar removal) has an indeterminate superficial partial thickness wound that would otherwise have been incorrectly diagnosed as a deep partial thickness wound.'' The applicant suggested that deep partial thickness wounds require autografting. The applicant noted that the Phase 3 clinical trial NCT00324311 of patients with DPT and FT thickness had burns ranging from 5–30%TBSA.[446] The applicant claimed that it can be estimated that approximately 16.2% of NexoBrid™ treated wounds (34.1% autograft rate in standard of care group minus 17.9% autograft rate in the NexoBrid™ treated group) would have been autografted had other standard of care methods for burn debridement been used.

The applicant asserted that the use of NexoBrid™ as a non-surgical option for treatment reduces potential adverse events that may be associated with surgery or general anesthesia such as blood loss. The applicant noted that in the DETECT trial, median blood loss during eschar removal was significantly higher in the standard of care arm compared with NexoBrid™. It also noted that the NCT00324311 trial demonstrated smaller reductions in hemoglobin and hematocrit values before and after treatment in the NexoBrid™ arm compared to the standard of care arm.

The applicant asserted that the use of NexoBrid™ may reduce instances of surgical escharotomies which may be needed when a circumferential eschar produces a tourniquet effect that compromises circulation or movement.[447] [448] [449] According to the applicant, this requires an emergency escharotomy involving incising through areas of burnt skin to release the eschar and its constrictive effects, restore distal circulation, and allow adequate ventilation. The applicant claimed that reducing the need for an escharotomy also reduces the need for subsequent surgical reconstruction of the escharotomy wound, and potential complications, including uncontrolled bleeding, incomplete release, damage to deep structures, functional deficits, and scarring.

To support the claim that NexoBrid™ reduces the time to eschar removal, the applicant asserted that NexoBrid™ has been shown in the two phase 3 multi-center, randomized-controlled trials to have a lower average time of eschar removal compared to the standard of

[441] Hansbrough, J. F., et al. (1995). Wound healing in partial-thickness burn wounds treated with collagenase ointment versus silver sulfadiazine cream. *The Journal of burn care & rehabilitation, 16*(suppl_3_pt_1), 241–247.

[442] Klasen, H. J. (2000). A historical review of the use of silver in the treatment of burns. II. Renewed interest for silver. *Burns, 26*(2), 131–138.

[443] Soroff, H. S., & Sasvary, D. H. (1994). Collagenase ointment and polymyxin B sulfate/bacitracin spray versus silver sulfadiazine cream in partial-thickness burns: a pilot study. *The Journal of burn care & rehabilitation, 15*(1), 13–17.

[444] NexoBrid Draft Labeling Text

[445] Rosenberg, L., et al, A novel rapid and selective enzymatic debridement agent for burn wound management: A multi-center RCT. Burns 2014, Vol 40(3): 466–474.

[446] Ibid. Rosenberg, L., et al, A novel rapid and selective enzymatic debridement agent for burn wound management: A multi-center RCT. Burns 2014, Vol 40(3): 466–474.

[447] Kreiger et al, Efficacy of enzymatic debridement of deeply burned hands. Burns 2012, Vol 38: 108–112.

[448] Giudice et al, Cost Analysis of a Novel Enzymatic Debriding Agent for Management of Burn Wounds. Biomed Res Int 2017, Vol 2017.

[449] Palao et al, Use of a selective enzymatic debridement agent (NexoBrid®) for wound management: Learning curve. World J of Dermatology 2017, Vol 6(2): 32–41.

care, with the DETECT study demonstrating 1.0 day eschar removal versus 3.8 days and NCT00324311 demonstrating 2.2 days versus 8.7 days (p<0.0001) for treated and control groups respectively.[450]

The applicant also included a systematic review and meta-analysis of clostridial collagenase ointment (CCO) studies by Pham, C. H., et al. to support its claim of decreased eschar removal time as compared to existing non-surgical therapies.[451] Per the study, the reported average time to clean wound bed (complete eschar removal) for CCO ranged from 6 days to 9.3 days with daily dressing changes among the prospective studies included in the systematic review. We note that the literature review was limited to the efficacy and use of CCO in burn patients and did not discuss other standard of care therapies.

The applicant asserted that the use of NexoBrid™ can lead to decreased need for surgical excision. The applicant stated that in a pooled analysis of both Phase 3 clinical trials, NexoBrid™ exhibited lower incidence of surgical excision to complete eschar removal (26.9% vs 70.6%), lower mean percent wound area surgically excised (11.5% vs 55.1%), and a higher rate of complete eschar removal without rescue surgical excision (90.5% vs 70.1%) compared to standard of care. The applicant cited these results as proof of the tissue-sparing effects compared with standard of care. The applicant further stated that the NCT00324311 study [452] showed that among patients with wounds comprised entirely of deep partial thickness (DPT) burns in this study, the incidence of excision or dermabrasion after debridement was statistically significantly lower with NexoBrid™ compared with standard of care (15.1% vs 65.5%, p<0.0001), and that the mean percent wound area excised was also statistically significantly lower with NexoBrid™, 14.6% versus 44.5% in standard of care group (p <0.0001). The applicant stated that in the DETECT study, the incidence of complete eschar removal in the NexoBrid™ group was 93.35% (70 of 75 patients) versus 100% in the standard of care group (which included both surgical and non-surgical debridement) versus 4.0% in the gel vehicle placebo group. The applicant stated that the incidence of excision to complete eschar removal was statistically significantly lower with NexoBrid™, 4.0% versus 72% for the standard of care group (p<0.0001).

The applicant asserted that the shorter time to complete eschar removal for patients treated with NexoBrid™ has been shown to be associated with effective prevention of the subsequent need for autografting. The applicant stated that in the first published Phase 3 pivotal clinical trial NCT00324311,[453] the autograft rate was 17.9% in the NexoBrid™ treated arm vs. 34.1% in the standard of care treated group (p=0.009), and the percentage of wound autografted was lower in the NexoBrid™ group, 8.4% vs. 21.5% in the standard of care group (p=0.0054). The applicant further stated that among patients with at least one wound that was entirely a DPT burn, significantly fewer wound autografts were performed in the NexoBrid™ group, 17.9% (19/106 wounds) versus 34% (30/88 wounds) in the standard of care group (p=0.0099), and the percent treated wound area autografted was also significantly lower in the NexoBrid™ group, 8.4% versus 21.5% in the standard of care group (p=0.0054).

The applicant also stated that a prospective single-arm study of NexoBrid™ showed that 25 patients with partial thickness burns who were treated with NexoBrid™ experienced a reduction in the need for autografting compared to patients treated with standard of care.[454]

The applicant also cited studies comparing NexoBrid™ to surgical debridement in hand and facial burns. The applicant stated that a single center controlled study of 40 hand burns demonstrated a reduced need for autografting with NexoBrid™, with 15% of patients receiving NexoBrid™ compared to 95% of patients treated with the standard of care (excisional surgical debridement) requiring autografting (p=0.034).[455] The single center controlled study of 26 face burns demonstrated a reduced need for autografting with NexoBrid®, with 15% of patients receiving NexoBrid™ compared to 77% of patients treated with the standard of care requiring autografting (p=−0.002).[456]

The applicant asserted that because the use of NexoBrid™ reduces areas that require autografting, this results in decreased donor site morbidity, which is particularly useful for patients with limited donor site area (example, high total body surface area burns), or risk factors for delayed wound healing (example, advanced age).[457] [458]

Per the applicant, by selectively debriding only non-viable tissue, NexoBrid™ reduces the area of burn that requires autografting compared to surgical excision and other non-surgical approaches of eschar debridement. Per the applicant, NexoBrid™'s selective debridement of non-viable tissue is especially useful in delicate areas such as face,[459] hands,[460] [461] feet, and genitals which are difficult areas to excise eschar surgically.[462] [463] The applicant also claimed that the use of NexoBrid™ results in decreased scarring from the reduced need for autografting.

The applicant asserted that the two single-center controlled trials discussed in this section, one of patients with hand burns[464] and one of patients with

[450] Rosenberg, L., et al, A novel rapid and selective enzymatic debridement agent for burn wound management: A multi-center RCT. Burns 2014, Vol 40(3): 466–474.

[451] [Insert cite]

[452] Rosenberg, L., et al, A novel rapid and selective enzymatic debridement agent for burn wound management: A multi-center RCT. Burns 2014, Vol 40(3): 466–474.

[453] Rosenberg, L., et al, A novel rapid and selective enzymatic debridement agent for burn wound management: A multi-center RCT. Burns 2014, Vol 40(3): 466–474.

[454] Palao, R., et al. (2017). Use of a selective enzymatic debridement agent (NexoBrid®) for wound management: Learning curve. World Journal of Dermatology, 6(2), 32–41.

[455] Schulz, A., et al. (2017). Enzymatic versus traditional surgical debridement of severely burned hands: a comparison of selectivity, efficacy, healing time, and three-month scar quality. *Journal of Burn Care & Research, 38*(4), e745-e755.

[456] Schulz, A., et al. (2017). Enzymatic debridement of deeply burned faces: healing and early scarring based on tissue preservation compared to traditional surgical debridement. *Burns, 43*(6), 1233–1243.

[457] Holmes Iv, J. H., et al. (2018). A comparative study of the ReCell® device and autologous split-thickness meshed skin graft in the treatment of acute burn injuries. *Journal of Burn Care & Research, 39*(5), 694–702.

[458] Gould, L., et al. (2015). Chronic wound repair and healing in older adults: current status and future research. *Wound Repair and Regeneration, 23*(1), 1–13.

[459] Schulz, A., et al. (2017). Enzymatic debridement of deeply burned faces: healing and early scarring based on tissue preservation compared to traditional surgical debridement. *Burns, 43*(6), 1233–1243.

[459] Rosenberg et al, A novel rapid and selective enzymatic debridement agent for burn wound management: A multi-center RCT. Burns 2014, Vol 40(3): 466–474.

[460] Schulz, A., et al. (2017). Enzymatic versus traditional surgical debridement of severely burned hands: a comparison of selectivity, efficacy, healing time, and three-month scar quality. *Journal of Burn Care & Research, 38*(4), e745–e755.

[461] Krieger, Y., et al. (2012). Efficacy of enzymatic debridement of deeply burned hands. *Burns, 38*(1), 108–112.

[462] Cordts, T., et al. (2016). Enzymatic debridement for the treatment of severely burned upper extremities–early single center experiences. *BMC dermatology, 16*(1), 1–7.

[463] Hirche, C., et al. (2020). Eschar removal by bromelain based enzymatic debridement (NexoBrid®) in burns: European consensus guidelines update. *Burns.*

[464] Schultz et al, Enzymatic Versus Traditional Surgical Debridement of Severely Burned Hands: A Comparison of Selectivity, Efficacy, Healing Time, and Three-Month Scar Quality. J Burn Care and Research 2016, Vol 38(4): 745–755.

facial burns,[465] demonstrated that cosmesis of the healed wound using NexoBrid™ was comparable if not better than traditional surgical debridement (standard of care arm). In addition, per the applicant, a single arm prospective study of 36 patients showed that only 11.1% of patients treated with NexoBrid™ developed hypertrophic scars.[466]

In further support of their statements suggesting that the use of NexoBrid™ results in reduced time to complete debridement, reduced need for surgery, and reduced need for autografting, the applicant submitted a literature review that identified studies published between 2012 and 2017 involving the use of NexoBrid™ in deep partial and full thickness burns.[467] In this article, studies were evaluated for proposed benefits of NexoBrid™ and categorized under supporting evidence, contradicting evidence, and anecdotal opinions. Seven prospective studies met the inclusion criteria including four randomized controlled trials. Six proposed benefits associated with the use of NexoBrid™ were extracted from the studies including reduced time to complete debridement, need for surgery, area of burns excised, need for autograft, time to wound closure, and improved scar quality. The authors of the literature review stated that most of the proposed benefits had strong supporting evidence from controlled trials as well as some anecdotal data. The authors further stated that for the proposed benefits of scar quality improvement and reduced time to wound healing, three sources and one anecdotal study provided refuting evidence. Incidence of pain was also evaluated and was mainly anecdotal, lacking formal objective assessment or cohort study.[468]

Regarding the substantial clinical improvement criterion, we have the following concerns. We note that the applicant's claims of superiority of NexoBrid™ to standard of care debridement methods are non-specific because the studies cited were not designed to compare NexoBrid™ to a specific non-surgical method or an enzymatic debridement product. In addition, we are unclear whether comparing NexoBrid™ to a surgical treatment modality is the most appropriate comparator since mechanical means of debridement have different clinical indications, risks, and benefits compared to enzymatic debridement. We note that studies also did not demonstrate that NexoBrid™ selectively debrides eschar and does not injure viable skin. In addition, it may be difficult to generalize across studies of NexoBrid™ because the wound care and timing of the debridement and subsequent autografting varies across different burn centers and studies. We note that we are unable to verify the results of the DETECT study as it does not appear that this data has been published or provided by the applicant. Finally, we note that a review of seven studies of NexoBrid™ [469] observed that when compared to the standard of care, there were variable reports of the cosmetic outcome of NexoBrid™, prolonged wound closure, longer lengths of stay, and significant pain associated with NexoBrid™ eschar debridement.

We invite public comment on whether NexoBrid™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the NexoBrid™.

m. Olumiant® (baricitinib)

Eli Lilly and Company submitted an application for new technology add-on payments for Olumiant® (baricitinib) for FY 2022. Olumiant® is a Janus kinase (JAK) 1 and 2 inhibitor used in combination with remdesivir as a treatment option for coronavirus disease 2019 (COVID–19), a respiratory disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2). Olumiant® has not yet received marketing approval from FDA to treat COVID–19, but has received an emergency use authorization (EUA) by the FDA. Olumiant® has been previously approved by FDA for the treatment of adult patients with moderately to severely active rheumatoid arthritis, who have had inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.[470]

The applicant stated that patients diagnosed with COVID–19 are at an elevated risk for excess morbidity and mortality due to the underlying SARS-CoV–2 infection and subsequent cytokine activation. The applicant stated that the cause of respiratory failure in COVID–19 is a hyperinflammatory state characterized by upregulation of multiple cytokines and that Olumiant® may be a viable treatment in patients with COVID–19 requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) because of its anti-inflammatory activity and ability to reverse dysregulated inflammatory markers in patients with COVID–19.[471] The applicant noted treatment with baricitinib 4 mg resulted in reduced plasma levels of the cytokine IL–6 in hospitalized patients with COVID–19, a finding that was replicated after being observed in patients with rheumatoid arthritis.[472] [473] [474] The applicant also claimed that Olumiant® potentially has anti-viral activity in inhibiting SARS-CoV–2 from entering and infecting lung cells due to its affinity for adaptor-associated kinase-1 (AAK1).[475] The applicant noted that there are ongoing

[465] Schultz et al, Enzymatic debridement of deeply burned faces: Healing and early scarring based on tissue preservation compared to traditional surgical debridement. Burns 2017b, Vol 43(2017): 1233–1243.

[466] Corrales-Benitez et al, Reduced need for grafting and low incidence of hypertrophic scarring in burns after enzymatic debridement. J. Plastic Surgery Latin America 2016, Vol 42(4).

[467] Loo, Y. L., Goh, B. K., & Jeffery, S. (2018). An overview of the use of bromelain-based enzymatic debridement (NexoBrid®) in deep partial and full thickness burns: appraising the evidence. *Journal of Burn Care & Research,* 39(6), 932–938.

[468] Loo, Y. L., Goh, B. K., & Jeffery, S. (2018). An overview of the use of bromelain-based enzymatic debridement (NexoBrid®) in deep partial and full thickness burns: appraising the evidence. *Journal of Burn Care & Research, 39*(6), 932–938.

[469] Loo, Y.L., et al, An Overview of the Use of Bromelain-Based Enzymatic Debridement (NexoBrid®) in Deep Partial and Full Thickness Burns: Appraising the Evidence. J Burn Care and Research 2018, Vol 39(6): 932–938.

[470] Olumiant (baricitinib) [package insert]. US Food and Drug Administration. Available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/207924s002lbl.pdf*. Revised July 8, 2020. Accessed October 8, 2020.

[471] McInnes IB, Byers NL, Higgs RE, et al. Comparison of baricitinib, upadacitinib, and tofacitinib mediated regulation of cytokine signaling in human leukocyte subpopulations. Arthritis Res Ther. 2019;21(1):183. *https://doi.org/10.1186/s13075–019–1964–1*.

[472] Bronte V, Ugel S, Tinazzi E, et al. Baricitinib restrains the immune dysregulation in severe COVID–19 patients [published online August 18, 2020]. J Clin Invest. *https://doi.org/10.1172/JCI141772*.

[473] Sims JT, Krishnan V, Chang CY, et al. Characterization of the cytokine storm reflects hyperinflammatory endothelial dysfunction in COVID–19 [published online September 10, 2020]. J Allergy Clin Immunol. *https://doi.org/10.1016/j.jaci.2020.08.031*.

[474] Stebbing J, Krishnan V, de Bono S, et al; Sacco Baricitinib Study Group. Mechanism of baricitinib supports artificial intelligence-predicted testing in COVID–19 patients. EMBO Mol Med. 2020;12(8):e12697. *https://doi.org/10.15252/emmm.202012697.*

[475] Richardson P, Griffin I, Tucker C, Smith D, Oechsle O, Phelan A, Rawling M, Savory E, Stebbing J. Baricitinib as potential treatment for 2019-nCoV acute respiratory disease. Lancet. 2020 Feb 15; 395(10223):e30–e31. doi: 10.1016/S0140–6736(20)30304–4. Epub 2020 Feb 4. Erratum in: Lancet. 2020 Jun 20; 395(10241):1906. PMID: 32032529; PMCID: PMC7137985.

studies to evaluate the impact of the antiviral host activity of Olumiant®.

With respect to the newness criterion, Olumiant® received Emergency Use Authorization (EUA) from FDA on November 19, 2020 for the emergency use of Olumiant®, indicated for use in combination with remdesivir for the treatment of suspected or laboratory confirmed COVID–19 in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The applicant stated that it intends to submit a supplemental new drug application (sNDA) for Olumiant®.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

We also refer the reader to our comment solicitation in section II.F.7 of the preamble of this proposed rule regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA. With respect to Olumiant®, we are specifically requesting comment on whether the newness period for this technology would begin on November 19, 2020, the date of its EUA, when the product became available on the market.

In response to the COVID–19 public health emergency (PHE), we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71155). We believe that as drugs and biological products become available and are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.[476] Qualifying inpatient cases involving the use of Olumiant®, in combination with VEKLURY®, are currently eligible for NCTAP beginning November 19, 2020, the date Olumiant® received EUA, through the end of the PHE.

We anticipate that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned MS–DRG may not adequately reflect the additional cost of new COVID–19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we believe that the NCTAP should remain available for cases involving eligible treatments, including Olumiant®, in combination with VEKLURY®, for the remainder of the fiscal year in which the PHE ends (for example, until September 30, 2022). We refer the reader to our proposal in section II.F.8. of the preamble of this proposed rule to extend the NCTAP through the end of the fiscal year in which the PHE ends for certain products and discontinue the NCTAP for products approved for new technology add-on payments in FY 2022.

The applicant indicated that Olumiant® could be reported using the ICD–10–PCS codes 3E0DXGC (Introduction of other therapeutic substance into mouth and pharynx, external approach) or 3E0G7GC (Introduction of other therapeutic substance into upper GI, via natural or artificial opening) but stated that these codes do not uniquely identify the administration of Olumiant®. We note that ICD–10–PCS codes XW0DXF5 (Introduction of other new technology therapeutic substance into mouth and pharynx, external approach, new technology group 5) and 3E0H7GC (Introduction of other therapeutic

[476] Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 71142, 71155 (November 6, 2020). *https://www.govinfo.gov/content/pkg/FR-2020-11-06/pdf/2020-24332.pdf.*; For more information on NCTAP, refer to CMS' provider toolkit at *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap.*

substance into lower G.I. via natural or artificial opening) could also be used to report use of Olumiant®. We note that as of January 1, 2021, Olumiant® is uniquely identified by ICD–10–PCS codes XW0DXM6 (Introduction of baricitinib into mouth and pharynx, external approach, new technology group 6), XW0G7M6 (Introduction of baricitinib into upper GI, via natural or artificial opening, new technology group 6), and XW0H7M6 (Introduction of baricitinib into lower GI, via natural or artificial opening, new technology group 6).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Olumiant® does not use the same or a similar mechanism of action when compared to an existing technology to achieve a therapeutic outcome, as there are no JAK inhibitor therapies that have received an EUA or an approval from FDA to treat COVID–19.

The applicant notes that currently there is one therapy approved by FDA to treat COVID–19 in hospital inpatients, remdesivir, and one therapy, besides Olumiant®, that has received EUA for the treatment of COVID–19, convalescent plasma.[477] The applicant claims that the mechanism of action for both of these treatments differs from Olumiant®, which works as a JAK inhibitor.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that there are no JAK inhibitor therapies that have received an EUA or an approval from FDA for the treatment of patients with COVID–19 and that Olumiant® could therefore not be assigned to the same MS–DRG as existing technologies.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, Olumiant® represents a potential new treatment option for adult and pediatric patients 2 years or older with suspected or laboratory-confirmed COVID–19 requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The applicant also stated that COVID–19 is an entirely distinct disease from those caused by other coronaviruses including severe acute respiratory syndrome (SARS) and the Middle East respiratory syndrome coronavirus (MERS–CoV).

In summary, the applicant asserted that Olumiant® is not substantially similar to other available therapies because, as a JAK inhibitor, it has a unique mechanism of action; there are no other products assigned to the same MS–DRG; and it treats a different patient population and disease—COVID–19. However, although there may not be any other JAK inhibitors for the treatment of COVID–19 assigned to the same MS–DRG as Olumiant®, we note that Olumiant® may map to the same MS–DRG as other existing COVID–19 treatments. We also note that Olumiant® involves the treatment of the same patient population and disease as other treatments for COVID–19, as Olumiant® is given to the same patients as remdesivir due to the EUA indication.

As discussed in section II.F.7 of the preamble, we are requesting comment regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA. We are also specifically requesting comment on whether the newness period for Olumiant® would begin on November 19, 2020, the date of its EUA, when the product became available on the market.

As previously discussed, under the regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

We are inviting public comment on whether Olumiant® meets the newness criterion.

With respect to the cost criterion, the applicant performed four analyses. Two of these analyses were based on proxy COVID–19 cases using ICD–10–CM B97.29 with additional coding to identify manifestation. The applicant stated that these cases were then differentiated into proxy COVID–19 cases with supplemental oxygen and all proxy COVID–19 cases. The applicant stated that they also conducted two supplemental analyses to confirm that actual COVID–19 cases using Olumiant® would meet the cost threshold using linked 837 and 835 inpatient Electronic Data Interchange (EDI) transaction sets that were processed during February through June of 2020. The applicant then identified COVID–19 cases with supplemental oxygen and all COVID–19 cases.

For the first analysis, the applicant searched the FY 2019 MedPAR LDS claims data file for potential cases representing patients who may be eligible for treatment using Olumiant®. The applicant identified proxy COVID–19 cases with supplemental oxygen by using ICD–10–CM diagnosis code B97.29 with one of the following ICD–10–CM codes: J12.89, J20.8, J40, J22, J98.8, and J80. The applicant excluded ICD–10–CM codes B34.2 and Z03.818. The applicant stated that this coding methodology was based on CDC guidance for coding COVID–19 cases prior to April 1, 2020. The applicant then limited the group to those cases that had ICD–10–PCS codes for supplemental oxygen. The ICD–10–PCS codes included ventilation (5A1935Z, 5A1945Z, 5A1955Z, 5A09357, 5A09358, 5A09359, 5A0935B, 5A0935Z, 5A09457, 5A09458, 5A09459, 5A0945B, 5A0945Z, 5A09557, 5A09558, 5A09559, 5A0955B, and 5A0955Z), extracorporeal membrane oxygenation (5A15223, 5A1522F, 5A1522G, 5A1522H, 5A15A2F, 5A15A2G, and 5A15A2H), and ICD–10–CM code Z99.81. This resulted in 473 cases mapping to the 11 MS–DRGs listed below.

[477] The Federal Drug and Food Administration. Emergency Use Authorizations: Drug and Biological Products. 2020. *https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-useauthorization#coviddrugs.*

MSDRGs - Proxy COVID-19 with Supplemental Oxygen	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis w/o Mv >96 Hours w MCC
189	Pulmonary Edema & Respiratory Failure
193	Simple Pneumonia & Pleurisy w MCC
190	Chronic Obstructive Pulmonary Disease w MCC
208	Respiratory System Diagnosis w Ventilator Support <=96 Hours
870	Septicemia or Severe Sepsis w MV >96 Hours or Peripheral Extracorporea
291	Heart Failure & Shock w MCC or Peripheral Extracorporeal Membrane Oxyg
207	Respiratory System Diagnosis w Ventilator Support >96 Hours or Periphe
202	Bronchitis & Asthma w CC/MCC
177	Respiratory Infections & Inflammations w MCC
194	Simple Pneumonia & Pleurisy w CC

For the second analysis, the applicant identified all proxy COVID–19 cases using the same ICD–10–CM codes that were previously described; however, the applicant did not include or exclude any cases based on the ICD–10–PCS codes listed in claims. This resulted in 1,726 cases mapping to the following 25 MS–DRGs.

MSDRGs - All Proxy COVID-19	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis w/o Mv >96 Hours w MCC
193	Simple Pneumonia & Pleurisy w MCC
202	Bronchitis & Asthma w CC/MCC
189	Pulmonary Edema & Respiratory Failure
190	Chronic Obstructive Pulmonary Disease w MCC
291	Heart Failure & Shock w MCC or Peripheral Extracorporeal Membrane Oxygen
194	Simple Pneumonia & Pleurisy w CC
191	Chronic Obstructive Pulmonary Disease w CC
208	Respiratory System Diagnosis w Ventilator Support <=96 Hours
870	Septicemia or Severe Sepsis w MV >96 Hours or Peripheral Extracorporea
177	Respiratory Infections & Inflammations w MCC
872	Septicemia or Severe Sepsis w/o MV >96 Hours w/o MCC
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC
195	Simple Pneumonia & Pleurisy w/o CC/MCC
207	Respiratory System Diagnosis w Ventilator Support >96 Hours or Periphe
166	Other Resp System O.R. Procedures w MCC
203	Bronchitis & Asthma w/o CC/MCC
205	Other Respiratory System Diagnoses w MCC
682	Renal Failure w MCC
308	Cardiac Arrhythmia & Conduction Disorders w MCC
192	Chronic Obstructive Pulmonary Disease w/o CC/MCC
292	Heart Failure & Shock w CC
178	Respiratory Infections & Inflammations w CC
698	Other Kidney & Urinary Tract Diagnoses w MCC
280	Acute Myocardial Infarction, Discharged Alive w MCC

For the third analysis, the applicant used Inovalon provider-sourced pre- and post-adjudicated claims data to identify CY 2020 claims for COVID–19 cases that may be eligible for treatment involving Olumiant®. Specifically, the applicant used linked 837 and 835 inpatient Electronic Data Interchange (EDI) transaction sets that were processed between February and June of 2020. For discharges prior to April 1, 2020, the applicant identified cases using ICD–10–CM diagnosis code B97.29 with one of the following ICD–10–CM codes: J12.89, J20.8, J40, J22, J98.8, and J80. The applicant excluded ICD–10–CM codes B34.2 and Z03.818. For cases discharged on or after April 1, 2020, the applicant identified cases using ICD–10–CM code U07.1 and excluded codes B34.2 and Z03.818. The applicant then limited the group to those cases that had ICD–10–PCS codes for supplemental oxygen. The ICD–10–PCS codes included ventilation (5A1935Z, 5A1945Z, 5A1955Z, 5A09357, 5A09358, 5A09359, 5A0935B, 5A0935Z, 5A09457, 5A09458, 5A09459, 5A0945B, 5A0945Z, 5A09557, 5A09558, 5A09559, 5A0955B, and 5A0955Z) and extracorporeal membrane oxygenation (5A15223, 5A1522F, 5A1522G, 5A1522H, 5A15A2F, 5A15A2G, and 5A15A2H), and ICD–10–CM code Z99.81 Dependence on supplemental oxygen. This resulted in 966 cases, which were mapped to the following 7 MS–DRGs:

MSDRGs - COVID-19 with Supplemental Oxygen	
MS-DRG	**Description**
870	Septicemia or Severe Sepsis W MV >96 Hours or Peripheral Extracorporea
871	Septicemia or Severe Sepsis w/o MV >96 Hours w MCC
207	Respiratory System Diagnosis w Ventilator Support >96 Hours or Periphe
177	Respiratory Infections & Inflammations w MCC
208	Respiratory System Diagnosis w Ventilator Support <=96 Hours
004	Tracheostomy w MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck w/o Major O.R
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC

For the fourth analysis, the applicant identified all COVID–19 cases using the same ICD–10–CM diagnosis codes as previously described. For discharges prior to April 1, 2020, the applicant identified cases using ICD–10–CM diagnosis code B97.29 with one of the following ICD–10–CM codes: J12.89, J20.8, J40, J22, J98.8, and J80. The applicant excluded ICD–10–CM codes B34.2 and Z03.818. For cases discharged on or after April 1, 2020, the applicant identified cases using ICD–10–CM code U07.1 and excluded codes B34.2 and Z03.818. The applicant did not include or exclude any cases based on the ICD–10–PCS codes listed in claims. Based on this analysis, the applicant found 3,826 cases, which map to 21 MS–DRGs listed below.

MSDRGs – All COVID-19	
MS-DRG	**Description**
177	Respiratory Infections & Inflammations w MCC
871	Septicemia or Severe Sepsis w/o MVv >96 hours w MCC
870	Septicemia or Severe Sepsis w MV >96 Hours or Peripheral Extracorporea
207	Respiratory System Diagnosis w Ventilator Support >96 Hours or Periphe
178	Respiratory Infections & Inflammations w CC
208	Respiratory System Diagnosis w Ventilator Support <=96 Hours
193	Simple Pneumonia & Pleurisy w MCC
179	Respiratory Infections And Inflammations w/o CC/MCC
004	Tracheostomy w MV >96 Hours or Principal Diagnosis Except Face, Mouth And Neck w/o Major O.R
194	Simple Pneumonia & Pleurisy w CC
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC
377	Gastrointestinal Hemorrhage w MCC
640	Miscellaneous Disorders Of Nutrition, Metabolism, Fluids and Electrolytes w MCC
682	Renal Failure w MCC
981	Extensive O.R. Procedure Unrelated to Principal Diagnosis w MCC
291	Heart Failure & Shock w MCC or Peripheral Extracorporeal Membrane Oxyg
480	Hip And Femur Procedures Except Major Joint w MCC
637	Diabetes w MCC
689	Kidney And Urinary Tract Infections w MCC
195	Simple Pneumonia & Pleurisy w/o CC/MCC
698	Other Kidney & Urinary Tract Diagnoses w MCC

For each analysis, the applicant then removed 12.5 percent of the length of stay charges from the relevant cases to estimate the reduction in charges due to decrease in number of hospitalization days that may be avoided through use of baricitinib. The applicant determined this percentage based on findings from the ACTT–2 trial,[478] sponsored by the National Institute of Allergy and Infection Diseases (NIAID), which found an improved median time to recovery from 8 to 7 days (that is, a 12.5 percent improvement).

For the first two analyses, the applicant then standardized the charges and applied a 2-year inflation factor of 1.131096 that the applicant stated was used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges. We note that the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges is 1.13218, which would have increased the inflated charges figure. For analysis three and four, the applicant standardized the charges and applied a one-year inflation factor of 6.4 percent, the one-year inflation factor published in the FY 2021 IPPS/LTCH PPS final rule.

For each analysis, the applicant then calculated and added the charges for Olumiant® by taking the estimated per patient cost of the drug, and converting it to a charge by dividing the costs by the national average CCR (cost-to-charge ratio) of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601).

In the first analysis, which included proxy COVID–19 with supplemental oxygen cases, the applicant computed a final inflated average case-weighted standardized charge per case of $88,728, which exceeded the average case-weighted threshold amount of $69,276.

In the second analysis, which included all proxy COVID–19 cases, the applicant computed a final inflated average case-weighted standardized charge per case of $68,562, which exceeded the average case-weighted threshold amount of $56,643.

In the third analysis, which included COVID–19 with supplemental oxygen cases, the applicant computed a final inflated average case-weighted

[478] Kalil, A.C., Patterson, T.F., Mehta, A.K., et al. Baricitinib plus remdesivir for adults with Covid-19. (2020). *New England Journal of Medicine.* DOI: 10.1056/NEJMoa2031994

standardized charge per case of $198,114, which exceeded the average case-weighted threshold amount of $123,238.

In the fourth analysis, which included all COVID–19 cases, the applicant computed a final inflated average case-weighted standardized charge per case of $99,870, which exceeded the average case-weighted threshold amount of $75,891.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both analyses described previously, the applicant asserted that the technology meets the cost criterion.

We invite public comments on whether Olumiant® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Olumiant® in combination with remdesivir represents a substantial clinical improvement over existing technologies because it improves time to recovery, improves the odds of improvement in clinical status at Day 15 after enrollment, and reduces mortality in the treatment of COVID–19 compared to remdesivir alone.[479] The applicant also stated that the combination of Olumiant® and remdesivir has a favorable risk/benefit profile in comparison to remdesivir alone. The applicant also claimed that Olumiant® improves respiratory function in patients treated with corticosteroids for SARS-CoV–2 pneumonia when compared with corticosteroids alone.

In support of these claims, the applicant submitted the results of the Adaptive COVID–19 Treatment Trial (ACTT–2)[480] which was a randomized, double-blind, placebo-controlled clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The ACTT–2 trial included 1,033 hospitalized patients with COVID–19 and assessed whether the combination of Olumiant® plus remdesivir was superior to remdesivir + placebo. There were 515 patients randomized to the treatment group and 518 to the control group. Of those in the treatment group, 507 (98.4 percent) received treatment as assigned. Of those in the control group, 509 (98.3 percent) received treatment as assigned. A total of 498 patients in the treatment group and 495 in the control group completed the trial through day 29, recovered, or died. The mean age of the patients was 55.4 years, and 63.1 percent were male. An ordinal scale was used in the study that identified the patient's baseline disease severity at enrollment and ranged from 1 (not hospitalized, no limitations on activities) to 8 (death). This scale is displayed in the table below. The intention-to-treat population included 706 patients with moderate disease (ordinal score of 4 [hospitalized, not requiring supplemental oxygen—requiring ongoing medical care] or 5 [hospitalized, requiring supplemental oxygen]) and 327 with severe disease (ordinal score of 6 [hospitalized, on non-invasive ventilation or high flow oxygen devices] or 7 [hospitalized, on mechanical ventilation or ECMO]). Patients received remdesivir intravenously as a 200-mg loading dose on day 1, followed by a 100-mg maintenance dose administered daily on days 2 through 10 or until hospital discharge or death. Baricitinib was administered as a 4-mg daily dose (either orally [two 2-mg tablets] or through a nasogastric tube) for 14 days or until hospital discharge.

Baseline Disease Severity Ordinal Scale	
1	Not hospitalized, no limitations on activities
2	Not hospitalized, limitation on activities and/or requiring home oxygen
3	Hospitalized, not requiring supplemental oxygen – no longer requires ongoing medical care
4	Hospitalized, not requiring supplemental oxygen – requiring ongoing medical care
5	Hospitalized, requiring supplemental oxygen
6	Hospitalized, on non-invasive ventilation or high flow oxygen devices
7	Hospitalized, on mechanical ventilation or ECMO
8	Death

In support of its claim that Olumiant® in combination with remdesivir improves time to recovery from COVID–19 compared to remdesivir alone, the applicant cited the primary outcome of the ACTT–2 study, which showed that the median time to recovery for the Olumiant® plus remdesivir (treatment) group was 7 days and the median time to recovery for remdesivir plus placebo (control) group was 8 days (rate ratio for recovery, 1.16 (1.01–1.32); p=0.03). Recovery was defined as the participant being well enough for hospital discharge, meaning the participant either no longer required supplemental oxygen or ongoing medical care in the hospital, or was no longer hospitalized at Day 29.

The applicant also stated that the median time to recovery among patients receiving noninvasive ventilation or high-flow oxygen (baseline ordinal score of 6) was 10 days for the treatment group and 18 days in the control group (rate ratio for recovery, 1.51; 95 percent CI, 1.10–2.08). The applicant stated that the median time to recovery was one day shorter among patients receiving supplemental oxygen (baseline ordinal score of 5) in the Olumiant® and remdesivir group (5 days vs. 6 days) rate ratio 1.17; CI, 0.98–1.39). The applicant noted that for those receiving mechanical ventilation or ECMO at enrollment (baseline ordinal score of 7), the rate ratio for recovery was 1.08 (95 percent CI, 0.59 to 1.97).

The applicant asserted that the secondary outcome of the ACTT–2 study supports its claim of improved odds of improvement in clinical status at Day 15 based on the eight-category ordinal scale. The applicant summarized the results of the study which showed that the odds of improvement in clinical status at Day 15 were greater in the Olumiant® group compared to the placebo group (odds ratio 1.3; 95 percent CI, 1.0–1.6). The applicant also stated that the odds of

[479] Kalil, A.C., Patterson, T.F., Mehta, A.K., et al. Baricitinib plus remdesivir for adults with Covid–19. (2020). *New England Journal of Medicine.* DOI: 10.1056/NEJMoa2031994.

[480] Ibid.

improvement in clinical status at Day 15 were greater for patients receiving noninvasive ventilation or high-flow oxygen (baseline ordinal score of 6) in the Olumiant® group versus the control group (odds ratio 2.2; 95 percent CI, 1.4–3.6).

The applicant asserted that the study conducted by Kalil et al. (2020) supports its claim of reduced mortality in the Olumiant® and remdesivir group compared to the control group because the Kaplan-Meier estimates of mortality at day 28 after randomization were 5.1 percent (95 percent CI, 3.5–7.6) in the combination (Olumiant® and remdesivir) group and 7.8 percent (95 percent CI, 5.7 to 10.6) in the control group (hazard ratio for death, 0.65; 95 percent CI, 0.39 to 1.09). The applicant also stated that the greatest numerical differences in mortality between patients in the combination group and those in the control group were observed among those with a baseline ordinal score of 5 (1.9 percent vs. 4.7 percent; hazard ratio, 0.40; 95 percent CI, 0.14 to 1.14) or 6 (7.5 percent vs. 12.9 percent; hazard ratio, 0.55; 95 percent CI, 0.22 to 1.38). The applicant also cited the Kaplan–Meier estimates of mortality at 14 days after randomization, which were 1.6 percent in the combination group and 3.0 percent in the control group (hazard ratio, 0.54; 95 percent CI, 0.23 to 1.28).

The applicant also asserted that the incidence of new use of oxygen was lower in patients treated with Olumiant® in combination with remdesivir compared to remdesivir alone (22.9 percent vs. 40.3 percent respectively; difference, −17.4 percentage points; 95 percent CI, −31.6 to −2.1) and that the incidence of new use of mechanical ventilation or ECMO was lower in the combination group (10.0 percent vs. 15.2 percent; difference, −5.2 percentage points; 95 percent CI, −9.5 to −0.9) based on Kalil et al. (2020). The applicant also stated that there were fewer median days of receipt of mechanical ventilation or ECMO among the 128 patients for which these interventions were started after enrollment or who died with no observed new use in the Olumiant® in combination with remdesivir group compared to the remdesivir group (16 median days in the combination group and 27 median days in the control group (difference, −11.0; 95 percent CI, −18.3 to −3.7)). The applicant also stated that the incidence of progression to death or noninvasive or invasive ventilation was lower in the combination group than in the control group (22.5 percent vs. 28.4 percent; rate ratio, 0.77; 95 percent CI, 0.60 to 0.98) and that the incidence of progression to death or invasive ventilation was also lower (12.2 percent vs. 17.2 percent; rate ratio, 0.69; 95 percent CI, 0.50 to 0.95).

The applicant asserted that the study conducted by Kalil et al. (2020) supports its claim that the combination of Olumiant® in combination with remdesivir has a favorable benefit/risk profile compared to remdesivir alone. The applicant states that serious adverse events occurred in 81 patients (16.0 percent) in the combination group (six of these were thought to be related to the trial product) and in 107 patients (21.0 percent) in the control group (five of these were thought to be related to the trial product) and the between-group difference was −5.0 percentage points (95 percent CI, −9.8 to −0.3; P = 0.03). The applicant also states that Grade 3 or 4 adverse events occurred in 207 patients (40.7 percent) in the combination group and 238 (46.8 percent) in the control group.

The applicant also cited an observational study [481] to support the claim that there was greater improvement in pulmonary function in patients receiving lopinavir/ritonavir and hydroxychloroquine with Olumiant® and corticosteroids when compared to patients receiving lopinavir/ritonavir and hydroxychloroquine with corticosteroids alone. In this study, the primary end point was the change in oxygen saturation as measured by pulse oximetry (SpO2)/FiO2 from hospitalization to discharge. The applicant stated that there was a greater improvement in SpO2/FiO2 from hospitalization to discharge observed in the Olumiant® in combination with corticosteriods versus the corticosteroids alone group (mean differences adjusted for IPSW, 49; 95 percent CI: 22, 77; p<0.001).

In our assessment of the applicant's claims in support of substantial clinical improvement, we have the following concerns. With regard to the ACTT–2 trial, we note that there were no statistically significant differences in time to recovery or odds of improvement in clinical status at Day 15 between the Olumiant®+remdesivir group compared to the remdesivir+placebo group for patients with a baseline ordinal score of 4, 5, or 7. We further note that although the applicant asserted that Olumiant®+remdesivir reduces mortality compared to remdesivir alone, the difference between the treatment and control groups was not statistically significant. We also note that the ACTT–2 study protocol prohibited the use of systemic corticosteroids for the treatment of COVID–19 but allowed systemic steroids for standard indications such as asthma exacerbation, acute respiratory distress syndrome (ARDS), chronic obstructive pulmonary disease (COPD), laryngeal edema, adrenal insufficiency and shock [482] and we are therefore unsure if the use of corticosteroids among the patient population may be a confounding factor. With regard to the Rodriguez-Garcia (2020) study, we note that this study did not involve the treatment of patients with Olumiant® in combination with remdesivir, which is the authorized use per its EUA, and the use of multiple treatments in this trial may make the effect of Olumiant® on greater improvement in pulmonary function unclear. Finally, we note that the current clinical guidelines from the Infectious Diseases Society of America (IDSA) recommend the use of Olumiant® with remdesivir rather than remdesivir alone among hospitalized patients with severe COVID–19 who cannot receive corticosteroids because of a contraindication.[483] In addition, guidelines from the National Institutes of Health (NIH) state that there are insufficient data to recommend for or against the use of Olumiant® in combination with remdesivir, where corticosteroids can be used instead, and there is insufficient data to recommend for or against the use of Olumiant®, in combination with corticosteroids.[484] We are therefore interested in data regarding the use of Olumiant® in combination with remdesivir over corticosteroids.

We welcome public comment on whether Olumiant® meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments

[481] Rodriguez, J.L., Sanchez-Niveas, G., Arevalo-Serrano, J., et al. (2020). Baricitinib improves respiratory function in patients treated with corticosteroids for SARS–CoV–2 pneumonia: An observational study. *Rheumatology*. 00:1–9.

[482] Ibid.

[483] Infectious Diseases Society of America. (2021, March 18). Recommendations 15–16: Baricitinib with remdesivir vs. remdesivir alone for hospitilized patients who cannot recieve corticosteriods due to contraindication. *IDSA Guidelines on the Treatment and Management of Patients with COVID–19*. Retrieved from *https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/*. * Severe patients defined as defined as patients with SpO_2 ≤94% on room air, including patients on supplemental oxygen, oxygen through a high-flow device, or non-invasive ventilation.

[484] National Institutes of Health. (2021, February 11). Kinase Inhibitors: Baricitinib and Other Janus Kinase Inhibitors, and Bruton's Tyrosine Kinase Inhibitors., *COVID–19 Treatment Guidelines*. Retrieved from *https://www.covid19treatmentguidelines.nih.gov/immunomodulators/kinase-inhibitors/*.

received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Olumiant®.

Comment: The applicant responded to questions elicited by its presentation at the New Technology Town Hall Meeting held in December 2020.

The applicant was asked to elaborate on the efficacy of Olumiant® and remdesivir as monotherapies versus in combination and how to think about appropriate use. The applicant stated that the evidence generated in randomized controlled clinical trials designed to evaluate remdesivir, Olumiant®, and the combination of Olumiant® and remdesivir has come primarily from the Adaptive Covid–19 Treatment Trial (ACTT) trials sponsored by NIAID. The applicant also stated that ACTT–1 was the first trial of the ACTT program and showed that remdesivir, when compared to placebo, is an effective treatment for hospitalized adult patients with coronavirus disease 2019 (Covid–19) pneumonia who were receiving standard of care as background treatment. The applicant stated that to address unmet medical needs still identified after the completion of ACTT–1 (namely morbidity and mortality due to Covid–19), ACTT–2 was designed to evaluate the combination of Olumiant® and remdesivir versus remdesivir in hospitalized adult patients with Covid–19 pneumonia who were receiving standard of care as background treatment. The applicant stated that the study did not evaluate Olumiant® alone; therefore, they do not have results generated by a RCT on the efficacy and safety profile of Olumiant® alone for the treatment of Covid–19 patients. The applicant stated that the ACTT–2 trial results show that the combination of Olumiant® was superior to remdesivir and placebo in reducing recovery time and accelerating improvement in clinical status among hospitalized patients with Covid–19, notably among those receiving high-flow oxygen or noninvasive ventilation.

The applicant was asked what the mechanism of action is for baricinitib's antiviral activity. The applicant stated that patients diagnosed with COVID–19 are at an elevated risk for excess morbidity and mortality due to the underlying severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) infection and subsequent cytokine activation. Management of COVID–19 is supportive; and respiratory failure from acute respiratory distress syndrome (ARDS) is the leading cause of mortality. The cause of respiratory failure in COVID–19 is a hyperinflammatory state characterized by upregulation of multiple cytokines. The applicant stated that in Wuhan, China, COVID–19-infected patients admitted to the ICU exhibited increased plasma concentrations of IL–2, IL–7, IL–10, GM–CSF, IP–10, MCP–1, MIP1-α, and TNF-α, compared with the non-ICU patients. Elevated IL–6 and hyperferritinemia were predictors of death in these patients with COVID–19.[485] [486] [487]

The applicant stated that Olumiant® may be a viable treatment in patients with COVID–19 requiring supplemental oxygen, invasive mechanical ventilation, or ECMO because of its anti-inflammatory activity and ability to reverse dysregulated inflammatory markers in patients with COVID–19.[488] [489] Relevant to COVID–19 and the potential role played by IL–6, the applicant stated that it is notable that treatment with Olumiant® 4 mg resulted in reduced plasma levels of IL–6 in hospitalized patients with COVID–19, a finding that was replicated after being observed in patients with RA.[490] [491] [492]

The applicant stated that the biochemical inhibitory effects of Olumiant® on human numb-associated kinase (NAK) members, responsible for SARS–CoV–2 viral propagation, measuring nanomolar affinities for AAK1, BIKE, and GAK were recently confirmed.[493] In addition, the applicant noted that some plasma markers that were dysregulated in moderate to severe hospitalized patients with COVID–19, that represent myeloid dysregulation, endothelial and cardiovascular inflammation, along with reduced antigen presenting plasmacytoid dendritic cells, were normalized over time with Olumiant® treatment.[494] The applicant stated that the impact of this antiviral host activity in patients with COVID–19 is being evaluated through collection of nasopharyngeal swabs, serum and whole blood for RNA, epigenetic analysis, and cellular phenotyping in the ongoing randomized Study KHAA.

The applicant stated that previous studies of corticosteroids in other viral pneumonias, especially SARS and Middle East respiratory syndrome (MERS), found an association with delayed viral clearance, and reinforced concerns that corticosteroids may impair host response to SARS–CoV–2.[495] [496] In contrast, treatment with Olumiant® from 2 distinct clinical case series indicate that the adaptive immune response responsible to generate IgG antibodies against SARS–CoV–2-specific spike proteins remains intact after treatment with Olumiant®.[497] [498] The applicant stated that the effects of corticosteroid treatment on adaptive immunity are

[485] Huang C, Wang Y, Li X, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet. 2020; 395(10223):497–506. *https://doi.org/10.1016/S0140-6736(20)30183-5.*

[486] Ruan Q, Yang K, Wang W, et al. Clinical predictors of mortality due to COVID–19 based on an analysis of data of 150 patients from Wuhan, China. Intensive Care Med. 2020; 46(5):846–848. *https://doi.org/10.1007/s00134-020-05991-x.*

[487] Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID–19 in Wuhan, China: A retrospective cohort study. Lancet. 2020;395(10229):1054–1062. *https://doi.org/10.1016/S0140-6736(20)30566-3.*

[488] McInnes IB, Byers NL, Higgs RE, et al. Comparison of baricitinib, upadacitinib, and tofacitinib mediated regulation of cytokine signaling in human leukocyte subpopulations. Arthritis Res Ther. 2019; 21(1):183. *https://doi.org/10.1186/s13075-019-1964-1.*

[489] Sims JT, Krishnan V, Chang CY, et al. Characterization of the cytokine storm reflects hyperinflammatory endothelial dysfunction in COVID–19 [published online September 10, 2020]. J Allergy Clin Immunol. *https://doi.org/10.1016/j.jaci.2020.08.031.*

[490] Bronte V, Ugel S, Tinazzi E, et al. Baricitinib restrains the immune dysregulation in severe COVID–19 patients [published online August 18, 2020]. J Clin Invest. *https://doi.org/10.1172/JCI141772.*

[491] Sims JT, Krishnan V, Chang CY, et al. Characterization of the cytokine storm reflects hyperinflammatory endothelial dysfunction in COVID–19 [published online September 10, 2020]. J Allergy Clin Immunol. *https://doi.org/10.1016/j.jaci.2020.08.031.*

[492] Stebbing J, Krishnan V, de Bono S, et al; Sacco Baricitinib Study Group. Mechanism of baricitinib supports artificial intelligence-predicted testing in COVID–19 patients. EMBO Mol Med. 2020; 12(8):e12697. *https://doi.org/10.15252/emmm.202012697.*

[493] Stebbing J, Krishnan V, de Bono S, et al; Sacco Baricitinib Study Group. Mechanism of baricitinib supports artificial intelligence-predicted testing in COVID–19 patients. EMBO Mol Med. 2020; 12(8):e12697. *https://doi.org/10.15252/emmm.202012697.*

[494] Sims JT, Krishnan V, Chang CY, et al. Characterization of the cytokine storm reflects hyperinflammatory endothelial dysfunction in COVID–19 [published online September 10, 2020]. J Allergy Clin Immunol. *https://doi.org/10.1016/j.jaci.2020.08.031.*

[495] Lee N, Allen Chan KC, Hui DS, et al. Effects of early corticosteroid treatment on plasma SARS associated coronavirus RNA concentrations in adult patients. J Clin Virol. 2004; 31(4):304–309. *https://doi.org/10.1016/j.jcv.2004.07.006.*

[496] Arabi YM, Mandourah Y, Al-Hameed F, et al; Saudi Critical Care Trial Group. Corticosteroid therapy for critically ill patients with Middle East Respiratory Syndrome. Am J Respir Crit Care Med. 2018; 197(6):757–767. *https://doi.org/10.1164/rccm.201706-1172OC.*

[497] Bronte V, Ugel S, Tinazzi E, et al. Baricitinib restrains the immune dysregulation in severe COVID–19 patients [published online August 18, 2020]. J Clin Invest. *https://doi.org/10.1172/JCI141772.*

[498] Stebbing J, Krishnan V, de Bono S, et al; Sacco Baricitinib Study Group. Mechanism of baricitinib supports artificial intelligence-predicted testing in COVID–19 patients. EMBO Mol Med. 2020; 12(8):e12697. *https://doi.org/10.15252/emmm.202012697.*

believed to occur through the non-canonical signaling pathways. The applicant asserted that the immunomodulatory pathway targeted by Olumiant®, JAK1/JAK2 signaling, opposed to NFKB (nuclear factor kappa-B cells) signaling targeted by corticosteroids, may offer an explanation to these effects.

The applicant also noted differences between Olumiant® and dexamethasone. The applicant stated that drugs acting on glucocorticoid receptors, such as dexamethasone, have a broad pathway approach to reduce inflammation that is known to be associated with profound immunosuppression, secondary hospital-acquired infections, gastrointestinal bleeding, hyperglycemia, and post-hospital neuromuscular weakness. JAK inhibitors, such as Olumiant®, act on several critical pathways to reduce inflammation while minimizing biological redundancy and have favorable PK properties and less immunosuppression.[499]

The applicant stated that the anti-inflammatory effects of Olumiant® have also been demonstrated by the reduction of serum levels of IFN-γ, IP–10, GM–CSF, and MCP–1 in pediatric patients with steroid-dependent chronic inflammation, resulting in control of disease activity and the ability to wean or taper steroids.[500] The applicant went on to state that, furthermore, dose-dependent decreases in IFN biomarkers confirmed an in vivo effect of Olumiant® on type-1 IFN signaling in pediatric patients suffering from CANDLE and SAVI.[501]

The applicant was asked if the adverse events were higher or unchanged among at risk subgroup populations over 65 years with comorbidities such as diabetes or chronic lung or renal disease in patients with COVID–19 and treated with Olumiant®. The applicant responded that there were 71 and 78 patients in the remdesivir+placebo groups and Olumiant®+remdesivir groups, respectively, who were over 65 years of age and had diabetes, chronic lung disease or renal disease in ACTT–2. The applicant stated that treatment emergent adverse events were reported in 62.0 percent of remdesivir+placebo and 57.7 percent of Olumiant®+remdesivir patients. Serious adverse events were reported in 33.8 percent of remdesivir+placebo and 28.2 percent of Olumiant®+remdesivir patients. The applicant stated that these findings are consistent with that in the overall population; fewer events in the Olumiant®+remdesivir group compared to remdesivir and placebo group.

Lastly, the applicant was asked to explain the difference in median time to recovery between patients who did not receive oxygen, which was 5 days in the Olumiant® and remdesivir group, and 4 days in the remdesivir and placebo group. For patients that did receive supplemental O2 and other respiratory interventions, the median time to recovery was shorter in those patients who received Olumiant® and remdesivir compared to the remdesivir and placebo group. The applicant replied that across all outcome measures, a more pronounced treatment effect was observed in patients with more severe disease at baseline. These data did not show additional benefit of adding Olumiant® to remdesivir for patients in the milder disease status. The applicant also stated that the ACTT–2 trial was not designed or powered to evaluate efficacy in each subgroup of patients per baseline ordinal scale. The applicant stated that these data led the applicant to request Emergency Use Authorization for Olumiant® and FDA authorized the use of Olumiant® in combination with remdesivir, for treatment of suspected or laboratory confirmed COVID–19 in hospitalized adults and pediatric patients 2 years of age or older, requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Response: We appreciate the applicant's comment. We will take the responses into consideration when deciding whether to approve new technology add-on payments for Olumiant®.

n. Pure-Vu® System

Motus GI holdings, Inc. submitted an application for new technology add-on payments for the Pure-Vu® System for FY 2022. The Pure-Vu® System is an FDA cleared system designed to connect to currently marketed colonoscopes to provide high intensity, intra-procedural cleansing of the colon during a colonoscopy. According to the applicant, the Pure-Vu® System is indicated for use in patients requiring therapeutic or diagnostic colonoscopies where the bowel has not been adequately prepared. The applicant asserted that the Pure-Vu® System would be used in situations such as a lower gastrointestinal bleed (LGIB), as LGIB does not allow for adequate bowel preparation.

The applicant asserted that the Pure-Vu® System device helps to avoid aborted and delayed colonoscopy procedures due to poor visualization of the colon mucosa by creating a unique High Intensity, Pulsed Vortex Irrigation Jet that consists of a mixture of air and water to break-up fecal matter, blood clots, and other debris, and scrub the walls of the colon while simultaneously removing the debris through two suction channels. The applicant stated that the suction channels have a sensor to detect the formation of a clog in the channels, triggering the system to automatically purge and then revert to suction mode once the channel is clear. According to the applicant, this combination of the agitation of the fluid in the colon via the pulsed vortex irrigation and simultaneous removal of the debris allows the physician to visualize the colon and achieve a successful colonoscopy or other advanced procedure through the colonoscope even if the patient is not properly prepped and has debris either blocking the ability to navigate the colon or covering the colon wall obscuring the mucosa and any pathology that may be present. The applicant asserted that the constant volume suction pumps do not cause the colon to collapse, which allows the physician to continue to navigate the colon while cleansing and avoids the need to constantly insufflate the colon, which may be required with other colonoscopy irrigation systems.

The applicant stated that the Pure-Vu® System is comprised of a workstation that controls the function of the system, a disposable oversleeve that is mounted on a colonoscope and inserted into the patient, and a disposable connector with tubing (umbilical tubing with main connector) that provides the interface between the workstation, the oversleeve, and off the shelf waste containers.

The applicant explained that the workstation has two main functions: Cleansing via irrigation and evacuation, and acting as the user interface of the system. The applicant explained that the irrigation into the colon is achieved by an electrical pump that supplies pressurized gas (air) and a peristaltic

[499] Stebbing J, Krishnan V, de Bono S, et al; Sacco Baricitinib Study Group. Mechanism of baricitinib supports artificial intelligence-predicted testing in COVID–19 patients. EMBO Mol Med. 2020; 12(8):e12697. *https://doi.org/10.15252/emmm.202012697.*

[500] Sanchez GAM, Reinhardt A, Ramsey S, et al. JAK1/2 inhibition with baricitinib in the treatment of autoinflammatory interferonopathies. J Clin Invest. 2018; 128(7):3041–3052. *https://doi.org/10.1172/JCI98814.*

[501] Kim H, Brooks KM, Tang CC, et al. Pharmacokinetics, pharmacodynamics, and proposed dosing of the oral JAK1 and JAK2 inhibitor baricitinib in pediatric and young adult CANDLE and SAVI patients. Clin Pharmacol Ther. 2018; 104(2):364–373. *https://doi.org/10.1002/cpt.936.*

pump that supplies the liquid (water or saline). According to the applicant, the pressurized gas and liquid flow through the ''main connector'' and are mixed upon entry into the umbilical tubing that connects to the oversleeve. The applicant explained that the gas pressure and flow are controlled via regulators and the flow is adjusted up or down depending on the cleansing mode selected. The applicant stated that a foot pedal connected to the user interface activates the main functions of the system so that the user's hands are free to perform the colonoscope procedure in a standard fashion.

The applicant stated that the evacuation mode (also referred to as suction) removes fecal matter and fluids out of the colon. The applicant noted that the evacuation function is active during cleansing so that fluid is inserted and removed from the colon simultaneously. The applicant explained that the evacuation pumps are designed in a manner that prevents the colon from collapsing when suctioning, which facilitates the ability to simultaneously irrigate and evacuate the colon. According to the applicant, during evacuation, the system continuously monitors the pressure in the evacuation channels of the oversleeve and if the pressure drops below pre-set limits the pumps will automatically reverse the flow. The applicant explained that the clog sensor triggers the system to automatically purge the material out of the channel and back into the colon where it can be further emulsified by the Pulsed Vortex Irrigation Jet, and then automatically reverts back into evacuation mode once the channel is cleared. The applicant stated that the evacuation (suction) that drains fecal matter and fluids out of the colon is generated by peristaltic pumps that can rotate in both directions, either to evacuate fluids and fecal matter from the colon through the evacuation tubes and into a waste container, or while in the reverse direction, to purge the evacuation tubes. The applicant claimed the suction created by this type of pump creates a constant volume draw of material from the colon and therefore prevents the colon from collapsing rapidly. According to the applicant, purging of evacuation tubes may be activated in two ways: The purging cycle is automatically activated when low pressure is noted by the evacuation-line sensor (it is also activated for the first 0.5 seconds when evacuation is activated to make sure the line is clear from the start); or a manual purge may be activated by the user by pushing the ''manual purge'' button on the foot pedal. The applicant claimed the pressure-sensing channel is kept patent by using an air perfusion mechanism where an electrical pump is used to perfuse air through the main connector and into the oversleeve, while the sensor located in the workstation calculates the pressure via sensing of the channel.

The applicant explained the Pure-Vu® System is loaded over a colonoscope and that the colonoscope with the Pure-Vu® Oversleeve is advanced through the colon in the same manner as a standard colonoscopy. The applicant stated that the body of the oversleeve consists of inner and outer sleeves with tubes intended for providing fluid path for the cleansing irrigation (2X), the evacuation of fluids (2X), the evacuation sensor (1X) and that the flexible head is at the distal end of the oversleeve and is designed to align with the colonoscope's distal end in a consistent orientation. The applicant explained that the distal cleansing and evacuation head contains the irrigation ports, evacuation openings, and a sensing port. According to the applicant, the system gives the physician the control to cleanse the colon as needed based on visual feedback from the colonoscope to make sure they have an unobstructed view of the colon mucosa to detect and treat any pathology. The applicant noted that since the Pure-Vu® System does not interfere with the working channel of the colonoscope, the physician is able to perform all diagnostic or therapeutic interventions in a standard fashion with an unobstructed field of view.

According to the applicant, multiple studies have shown that inadequate bowel visualization leads to missed pathology, delayed diagnosis, extended hospital stay, and in some cases, additional therapy being administered, especially in the acute LGIB population, which is the most common indication for inpatients that require colonoscopy.[502] [503] Unknown abdominal pain, infection, and foreign body removal were also cited by the applicant as being common indications for an inpatient colonoscopy.

The applicant explained that when a patient with LGIB is admitted to the hospital, they are stabilized and then started on bowel preparation for the colonoscopy procedure. The applicant claimed that the patient typically is placed on a liquid-only diet while consuming 4–6 liters of polyethylene glycol (PEG) based solution until the rectal effluent is clear. If the rectal effluent is not clear, additional bowel preparation is prescribed. The applicant stated that for severe LGIB cases, a patient is prescribed to consume a rapid purge of 1 liter every 30–45 minutes with a total volume of 4–14 liters, which could lead to purgative intolerance or vomiting. The applicant claimed that even in situations where bowel preparation has been completed, and clear rectal effluent while on a clear liquid diet has been confirmed, there are no guarantees that a patient's bowel is clean for a successful colonoscopy. The applicant submitted data from a study by the Cleveland Clinic showing 51 percent of 8,819 patients observed over a 4-year period were inadequately prepared for colonoscopies, leading to one extra day in the hospital compared to patients that were adequately prepared.[504] The applicant cited another study, by Northwestern University, demonstrating an association between inadequate bowel preparation and increased length of stay (LOS) in hospitals, with inadequately prepared patients staying two more days than adequately prepared patients on average.[505] The applicant claimed additional time spent in hospitals increases the patient's exposure to risks of hospital-acquired infections. The applicant claimed this risk is especially impactful to patients who are admitted for LGIB, which is seen at a higher prevalence in the elderly population.[506] [507] The applicant stated in the elderly population, continuous bowel preparation also poses increased risk due to their higher comorbidities and potential for electrolyte imbalances such as hyperphosphatemia, hypocalcemia, and hypokalemia.[508]

[502] Garber A, Sarvepalli S, Burke CA, Bhatt A, Ibrahim M, McMichael J, et al. Modifiable Factors Associated with Quality of Bowel Preparation Among Hospitalized Patients Undergoing Colonoscopy. J Hosp Med. 2019; 14(5):278–83.

[503] Yadlapati R, Johnston ER, Gregory DL, Ciolino JD, Cooper A, Keswani RN. Predictors of Inadequate Inpatient Colonoscopy Preparation and Its Association with Hospital Length of Stay and Costs. Dig Dis Sci. 2015; 60(11):3482–90.

[504] Garber A, Sarvepalli S, Burke CA, Bhatt A, Ibrahim M, McMichael J, et al. Modifiable Factors Associated with Quality of Bowel Preparation Among Hospitalized Patients Undergoing Colonoscopy. J Hosp Med. 2019; 14(5):278–83.

[505] Yadlapati R, Johnston ER, Gregory DL, Ciolino JD, Cooper A, Keswani RN. Predictors of Inadequate Inpatient Colonoscopy Preparation and Its Association with Hospital Length of Stay and Costs. Dig Dis Sci. 2015; 60(11):3482–90.

[506] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014; 20(47):17709–26.

[507] Hauck K, Zhao X. How dangerous is a day in hospital? A model of adverse events and length of stay for medical inpatients. Med Care. 2011; 49(12):1068–75.

[508] Parra-Blanco A, Ruiz A, Alvarez-Lobos M, Amoros A, Gana JC, Ibanez P, et al. Achieving the best bowel preparation for colonoscopy. World J Gastroenterol. 2014; 20(47):17709–26.

The applicant cited a practical guide authored by Kim B., et al., to assert that poor visualization of the colon mucosa has a direct effect on the ability to detect the presence of a GI bleed or the aftermath stigmata and administer treatment successfully.[509] The applicant used the Boston Bowel Preparation Scale (BBPS), developed by Lai E. et al,[510] as a reliable method to measure bowel preparation. The applicant stated that the scale is a range (0–9) of dirtiest to cleanest for the whole colon and 0 to 3 for each of the 3 segments of the colon; the right colon (including the cecum and ascending colon), the transverse colon (including the hepatic and splenic flexures), and the left colon (including the descending colon, sigmoid colon, and rectum). Therefore, the maximum BBPS score for a perfectly clean colon without any residual liquid is nine and the minimum BBPS score for an unprepared colon is zero. The points are assigned as follows: Zero = Unprepared colon segment with mucosa not seen due to solid stool that cannot be cleared; one = Portion of mucosa of the colon segment seen, but other areas of the colon segment not well seen due to staining, residual stool and/or opaque liquid; two = Minor amount of residual staining, small fragments of stool and/or opaque liquid, but mucosa of colon segment seen well; three = Entire mucosa of colon segment seen well with no residual staining, small fragments of stool or opaque liquid.

The applicant stated that evidence-based guidelines and clinical reviews in high impact biomedical journals recommend colonoscopy as the preferred initial modality for the diagnosis and treatment of acute lower gastrointestinal bleeding.[511] [512] The applicant stated that colonoscopy has been less frequently utilized than might otherwise be indicated because it suffers from the significant disadvantage of requiring the need for a large volume bowel preparation.[513] The applicant states that even with a bowel preparation, poor visualization often occurs because of a poorly prepared colon. Based on these assertions, the applicant inferred that colonoscopy for acute lower gastrointestinal bleeding would be much more utilized and lead to more diagnoses and interventions with intraprocedural bowel preparation, which puts the control of the visualization (cleanliness) of the colon mucosa in the hands of the endoscopist. The applicant further stated it is important to appreciate that alternatives to colonoscopy, including angiography and vascular embolization treatments to create hemostasis, have risks of ischemic vascular injury, retroperitoneal bleeding and acute renal injury.[514] The applicant stated that aside from the colonoscopy, other modalities such as tagged red blood cell scans, computed tomography (CT) angiograms, and mesenteric angiographies all require an active source of bleed in order to achieve a successful diagnostic yield. The applicant claimed that even when diagnosis is achieved using these modalities, a colonoscopy may still be ordered to treat the source of the bleed via epinephrine injections and clipping and thermal therapies, to prevent potential surgical interventions.

With respect to the newness criterion, the Pure-Vu® System first received FDA 510(k) clearance on September 22, 2016 under 510(k) number K60015. Per the applicant, this initial device was very cumbersome to set up and required direct support from the company and therefore was not viable for a small company with limited resources to market the device. The applicant noted that the initial device could have been sold starting on January 27, 2017 when the first device came off the manufacturing line. Per the applicant, the device was allocated for clinical evaluations but 10 institutions throughout the country purchased the device outside of a clinical study, primarily to allow physicians to try the product prior to committing to a clinical trial. The applicant further noted that minor modifications were made to the Pure-Vu System in additional 510(k) clearances dated December 12, 2017 and June 21, 2018. The current marketed Pure-Vu System was then granted 510(k) clearance on June 6, 2019 under 510(k) number K191220. Per the applicant, this clearance changed the entire set-up of the device, redesigned the user interface, and reduced the size, among other changes. According to the applicant, this updated version was commercially available as of September 19, 2019.

Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving the Pure-Vu® System. We note that the applicant has submitted a request for approval for a unique ICD–10–PCS code for the use of the Pure-Vu® System beginning FY 2022.

If a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the Pure-Vu® System has a different mechanism of action than existing technologies due to its ability to break up and remove a high volume of debris from the colon and dislodge adherent films from the colon wall in a safe manner that cannot be achieved with irrigation done through the working channel of a colonoscope. The applicant also asserted that due to the controlled simultaneous removal of the debris and fluid by the evacuation pumps in the system, the Pure-Vu® System eliminates the likelihood of creating a fluid load in the colon, which cannot be achieved with any other device on the market. The applicant further asserted a differing mechanism of action via the ability to sense and automatically clear a blockage versus manual suction through the working channel of a colonoscope, which can clog quickly if there is any appreciable debris. Lastly, the applicant explained that the Pure-Vu® System is an oversleeve device that allows use of the working channel of the colonoscope to be open and allows therapy to be administered in tandem with cleansing, unlike existing technologies on the market.

The applicant noted that the ClearPath system, a colonoscopy system by the company Easy Glide, received FDA clearance, but according to the applicant, was never fully brought to the US market. ClearPath was listed as the predicate device for the initial version of the Pure-Vu System® approved on September 22, 2016 (FDA 510(K) number K160015), in which both

[509] Kim BS, Li BT, Engel A, et al. Diagnosis of gastrointestinal bleeding: A practical guide for clinicians. World J Gastrointest Pathophysiol. 2014; 5(4):467–478.doi:10.4291/wjgp.v5.i4.467.

[510] Lai EJ, Calderwood AH, Doros G, Fix OK, Jacobson BC. The Boston Bowel Preparation Scale: A valid and reliable instrument for colonoscopy-oriented research. Gastrointestinal Endoscopy. 2009; 69(3):620–625.

[511] Strate LL, Gralnek IM. ACG Clinical Guideline: Management of Patients With Acute Lower Gastrointestinal Bleeding. Am J Gastroenterol. 2016 Apr;111(4):459–74. doi: 10.1038/ajg.2016.41. Epub 2016 Mar 1. Erratum in: Am J Gastroenterol. 2016 May;111(5):755. PMID: 26925883; PMCID: PMC5099081.

[512] Gralnek IM, Neeman Z, Strate LL. Acute Lower Gastrointestinal Bleeding. N Engl J Med. 2017 Mar 16;376(11):1054–1063. doi: 10.1056/NEJMcp1603455. PMID: 28296600.

[513] Carney BW, Khatri G, Shenoy-Bhangle AS. The role of imaging in gastrointestinal bleed. Cardiovasc Diagn Ther. 2019 Aug;9(Suppl 1):S88–S96. doi: 10.21037/cdt.2018.12.07. PMID: 31559156; PMCID: PMC6732104.

[514] Ibid. Carney BW, Khatri G, Shenoy-Bhangle AS. The role of imaging in gastrointestinal bleed. Cardiovasc Diagn Ther. 2019 Aug;9(Suppl 1):S88–S96. doi: 10.21037/cdt.2018.12.07. PMID: 31559156; PMCID: PMC6732104.

devices are described as able to irrigate and suction at any time during the procedure without any tools needing to be removed from the colonoscope working channel.[515] The applicant claimed that this system did not have the High Intensity Pulsed Vortex Irrigation Jet and controlled suction capabilities with the sensing and auto purge technology that is critical to get the desired clinical outcome.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the Pure-Vu System is assigned to the same MS–DRGs as existing technologies. The applicant lists 21 MS–DRGs as being applicable, with MS–DRG 378 (gastrointestinal hemorrhage with complication or comorbidity (CC)) accounting for 37.1 percent of cases, and MS–DRG 377 (gastrointestinal hemorrhage with major complication or comorbidity (MCC)) accounting for 18.9 percent of total cases.

With respect to the third criterion, whether the new use of technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that the Pure-Vu System® does involve treatment of the same or similar type of disease and patient population as existing technology.

After reviewing the information submitted by the applicant, we are unclear whether the Pure-Vu® System's mechanism of action is similar to that of the version of the product that received initial 510(k) clearance that was approved on September 22, 2016 or other versions of the system. In addition, with regard to the previous versions of Pure-Vu, we are unsure if the limited availability noted by the applicant would allow the technology to be considered commercially available. We are also unclear what the applicant means regarding the ClearPath system being not fully brought to the U.S. market. If the ClearPath system and/or earlier versions of the Pure-Vu System were considered to be available on the U.S. market, then we are concerned that the current version of Pure-Vu® would no longer be considered new, as we believe it may be substantially similar to ClearPath and/or earlier versions of the Pure-Vu® System because they also allow for irrigation and suction of the colon without utilizing the working channel. If the current version of Pure-Vu is substantially similar to ClearPath and/or previous versions, then it appears that the current Pure-Vu system may no longer be within the newness period. We further note that though the applicant states the Pure-Vu® System features a high intensity pulsed vortex irrigation jet and controlled suction capabilities with sensing and auto purge technology, the Pure-Vu® System irrigates the colon using water and gas like other existing irrigation methods. We are therefore uncertain as to whether these features of the Pure-Vu® System result in a new mechanism of action. We invite public comment on whether the Pure-Vu® System has a new mechanism of action compared to these predicate devices.

We are inviting public comments on whether the Pure-Vu® System is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file with the FY 2019 Final Rule with Correction Notice IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using the Pure-Vu® System. The applicant identified claims that reported an ICD–10–CM diagnosis code of ICD–10–CM Z12.11 (Encounter for screening for malignant neoplasm of colon), K92.2 (Gastrointestinal hemorrhage, unspecified), D50.0 (Iron deficiency anemia secondary to blood loss (chronic)), and C18._[516] (malignant neoplasm of colon). The ICD–10–PCS procedure codes listed in the following table were used to identify claims involving colonoscopy procedures.

ICD-10-PCS Code	Description
0DJD8ZZ	Inspection of lower intestinal tract, via natural or artificial opening endoscopic
0D5M8ZZ	Destruction of descending colon, via natural or artificial opening endoscopic
0D5N8ZZ	Destruction of sigmoid colon, via natural or artificial opening endoscopic
0D5L8ZZ	Destruction of transverse colon, via natural or artificial opening endoscopic
0D5K8ZZ	Destruction of ascending colon, via natural or artificial opening endoscopic
0W3P8ZZ	Control bleeding in gastrointestinal tract, via natural or artificial opening endoscopic

The claim search conducted by the applicant resulted in 163,236 claims mapping to 633 MS–DRGs. The applicant stated that MS–DRGs 377 (G.I. Hemorrhage W MCC), 378 (G.I. Hemorrhage W CC), and 379 (G.I. Hemorrhage W/O CC/MCC) were the most common MS–DRGs to which cases reporting the listed ICD–10–PCS codes were assigned. The applicant stated that the large number of DRGs to which these cases were assigned suggests that patients were admitted to the hospital for a wide variety of reasons, but during the course of their hospital stay the patients received a colonoscopy. According to the applicant, since GI bleeding is among the most common reasons for a patient needing an urgent colonoscopy, MS–DRGs 377–379 would be expected to be the most common MS–DRGs to which cases involving the Pure-Vu technology would be assigned. Lastly, the applicant did not have any data available to suggest any specific reasons why potential patients who would be eligible for the Pure-Vu technology would map to specific MS–DRGs identified based on the claims search, such as MS–DRG 291 (Heart Failure and Stroke).

The applicant determined an average unstandardized case weighted charge per case of $63,265.

The applicant did not remove charges for prior technology. The applicant stated that no prior technology is being replaced. The applicant then standardized the charges using the FY 2019 Final Rule with Correction Notice Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the new technology, the applicant used the national average CCR for the

[515] FDA. 2016, September. Pure Vu System 510(k) premarket notification. Deparment of Health and Human Services. Accessed at *https://www.accessdata.fda.gov/cdrh_docs/pdf16/K160015.pdf.*

[516] Fourth character is required to describe specific location of neoplasm.

Supplies and Equipment cost center of 0.297 from the FY 2021 Final IPPS rule. The applicant calculated a final inflated average case-weighted standardized charge per case of $93,914, which exceeded the average case-weighted threshold amount of $63,265 by $30,649. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for the Pure-Vu® System, we note that the MS–DRGs used in the cost analysis were not limited to those describing conditions likely to require a colonoscopy. For example, the applicant included cases assigned to MS–DRG 291 (Heart Failure and Shock with MCC). When included in the cost analysis, the assumption made is that all 1,948 cases for heart failure also had a colonoscopy performed where the technology could have potentially been utilized. We question whether all cases identified by the applicant appropriately represent potential cases eligible for the Pure-Vu® System. We invite public comment on whether the Pure-Vu® System meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Pure-Vu® System offers the ability to achieve rapid beneficial resolution of the disease process treatment by achieving rapid and full visualization of the colon, which will improve diagnostic yield and the effectiveness of treatment of diseases of the bowel. The applicant claimed that due to the Pure-Vu® System's ability to cleanse the colon during the colonoscopy procedure in conjunction with a standard bowel preparation, or with an enema (to allow entry into the rectum) and without any purgative based preparation, the technology allows for earlier intervention. The applicant stated that in the case of an LGIB, this will reduce bleeding by achieving more rapid hemostasis and reduce the overall length of stay in the hospital for a portion of this population. The applicant also asserted the technology reduces the subsequent diagnostic and, in some instances, therapeutic interventions by minimizing aborted and early repeat procedures due to poor visualization caused by inadequate preparation. The applicant stated that the system can provide cleansing and removal of fecal matter, blood and other debris while maintaining the visibility of the colonoscope's camera and availability of the working channel to apply critical therapies.

In support of its claims, the applicant submitted a self-sponsored, U.S.-based, multicenter, prospective, single arm study in the inpatient setting, analyzing 94 patients, 65 of which (68 percent) had a GI bleed.[517] Of the 94 patients (41 percent females/59 percent males), the mean age was 62 years. According to the applicant, the study's primary endpoint was the rate of improved bowel cleansing level from baseline to after use of the Pure-Vu® System per colon segment using the Boston Bowel Preparation Scale (BBPS). The BBPS score was recorded for each colorectal segment (left colon, transverse colon, and right colon segments) both prior to (baseline) and after colon cleansing with the Pure-Vu® System. An adequate cleansing level was *a priori* defined as a BBPS ≥2 in all evaluated colon segments. The study found that in 79 of the 94 patients (84 percent), the physician was able to successfully diagnose or rule out a GI bleed in the colon per the patients' colonoscopy indication using only the Pure-Vu® System. The analysis showed statistically significant visualization improvement in each colon segment after Pure-Vu® use with a mean BBPS score in the descending colon, sigmoid, and rectum of 1.74 pre-Pure-Vu® use and 2.89 post-Pure-Vu® use ($P<0.001$); in the transverse colon of 1.74 pre-Pure-Vu® use and 2.91 post Pure-Vu® use ($P<0.001$); and the ascending colon and cecum of 1.50 pre-Pure-Vu® use and 2.86 post Pure-Vu® use ($P<0.001$). The study found only 2 percent of cases where the diagnosis could not be achieved due to inadequate preparation. Overall, the 84 (89.4 percent) patients that received the Pure-Vu® System within the study improved BBPS scores from 38 percent (95 percent CI 28, 49) to 96 percent (95 percent CI 90, 99) in segments evaluated. The study noted one procedure related perforation which required surgical repair, and the patient was discharged 48 hours post operatively and recovered fully.

The applicant also provided three outpatient clinical studies to demonstrate the Pure-Vu® System's capability to convert patients to adequate preparation where preparation was previously inadequate, and the visualization was poor based on the BBPS. In the first study, Perez J., et al. conducted an outpatient prospective pilot study using the Pure-Vu® System.[518] The study observed 50 patients with poorly prepared colons undergoing colonoscopy at two outpatient clinical sites in Spain and Israel, respectively. The applicant claimed study patients underwent a reduced bowel preparation consisting of the following: No dried fruits, seeds, or nuts starting 2 days before the colonoscopy, a clear liquid diet starting 18 to 24 hours before colonoscopy, and a split dose of 20mg oral bisacodyl. The study found the number of patients with an adequate cleansing level (BBPS≥2 in each colon segment) increased significantly from 31 percent (15/49) prior to use of the Pure-Vu System (baseline) to 98 percent (48/49) after use of the Pure-Vu® System ($P<0.001$), with no serious adverse events reported.

In the second study provided by the applicant, van Keulen, et al. also conducted a single-arm, prospective study on 47 patients with a median age of 61 years in the outpatient setting in the Netherlands using the Pure-Vu® System.[519] Within the study, cecal intubation was achieved in 46/47 patients. This multicenter feasibility study found that the Pure-Vu® System significantly improved the proportion of patients with adequate bowel cleansing from 19.1 percent prior to the use of the Pure-Vu® System to 97.9 percent after its use ($P<0.001$) and median BBPS score (from 3.0 [IQR 0.0–5.0] to 9.0 [IQR 8.0–9.0]).

In the third study provided by the applicant that directly evaluated the Pure-Vu® System in a clinical setting, Bertiger G., et al. performed a United States-based single center, prospective, outpatient study investigating regimes of reduced outpatient bowel preparations, which included low doses of over-the-counter laxatives, and eliminating the typical 24 hour clear liquid diet restriction, which was replaced by a low residue diet the day before the procedure. In this study, 46 of a possible 49 patients received a colonoscopy, 8 of which took the over-the-counter laxative (''MiraLAX arm''), 21 patients ingested two doses of 7.5 oz Magnesium Citrate (MgC) each taken with 19.5 oz of clear liquid (''Mag Citrate 15 oz arm''), and 18 patients

[517] Helmut Neumann ML, Tim Zimmermann, Gabriel Lang, Jason B. Samarasena, Seth A. Gross, Bhaumik Brahmbhatt, Haleh Pazwash, Vladimir Kushnir. Evaluation of bowel cleansing efficacy in hospitalized patient population using the pure-vu system. Gastrointestinal Endoscopy. 2019;89(6).

[518] Perez Jimenez J, Diego Bermudez L, Gralnek IM, Martin Herrera L, Libes M. An Intraprocedural Endoscopic Cleansing Device for Achieving Adequate Colon Preparation in Poorly Prepped Patients. J Clin Gastroenterol. 2019;53(7):530–4.

[519] Van Keulen KE, Neumann H, Schattenberg JM, Van Esch AAJ, Kievit W, Spaander MCW, Siersema PD. A novel device for intracolonoscopy cleansing of inadequately prepared colonoscopy patients: A feasibility study. Endoscopy. 2019 Jan;51(1):85–92. doi: 10.1055/a–0632–1927. Epub 2018 Jul 11.

ingested 2 doses of 5 oz MgC taken with 16 oz of clear liquid (''Mag Citrate 10 oz arm''). Of the 46 subjects, 59 percent were males and there was a mean age of 61±9.48 years. The study found that each of the 3 study arms revealed significant differences in BBPS score between the baseline preparation and post-cleansing via Pure-Vu. All the preparation regimens resulted in inadequately prepped colons. Comparing the mean BBPS rating for both pre- and post- Pure-Vu® use, the MiraLAX arm was inferior (P <0.05) to both Mag Citrate arms. For the MiraLAX arm, the mean BBPS Score improved from 1.50 to 8.63. For the Mag Citrate 15 oz arm, the mean BBPS score improved from 3.62 to 8.95. For the Mag Citrate 10 oz arm, the mean BBPS Score improved from 4.76 to 9.0.

In addition to the retrospective studies provided, the applicant also submitted three case studies to highlight the various clinical presentations of LGIB with the use of the Pure-Vu® System. In the first case, the applicant presented a 71-year-old woman with multiple episodes of bloody bowel movements and low hemoglobin levels for 2 days after a screening colonoscopy where 8 polyps were removed. The applicant stated that the patient underwent a successful colonoscopy using Pure-Vu without standard inpatient bowel preparation within 5 hours, and in addition to expediting the colonoscopy, four significant post-polypectomy ulcers were found and clipped by allowing the physician to cleanse the area and place the clips simultaneously. The applicant claimed that since the Pure-Vu® System does not impact the use of the endoscope's working channel, the physician was able to cleanse the area as needed during the intervention to allow precise placement of the clips applied to achieve hemostasis and the patient was discharged that same day.

The applicant submitted another case example where a 52-year-old male was admitted from the emergency department to the ICU due to significant GI bleeding, hemorrhagic shock, and acute kidney injury (AKI) six days after a colonoscopy where nine polyps were removed, including two polyps greater than 2 cm. The applicant stated that angiographic control of the bleeding was not considered due to AKI with rising creatinine, and bedside colonoscopy was immediately performed with the Pure-Vu® System without any bowel prep. Per the applicant, the physician was able to visualize the entire colon to confirm all sources of bleeding and place two clips to obtain hemostasis, and the patient was downgraded out of the ICU that day and discharged from the hospital the following day.

In the third case study submitted by the applicant, a 64-year-old male was admitted to the ICU with one day of bright red blood per rectum (BRBPR) along with a complex set of disorders including but not limited to alcohol use disorder, heart failure with reduced ejection fraction of 30 percent, and multidrug resistant tuberculosis. The Pure-Vu® System was used to attempt to definitively identify the bleeding source in the ICU. The applicant stated that although no active sites of bleeding were seen, red blood was found in the entire colon, and the patient was transferred out of the ICU 2 days later and discharged 3 days after transfer to the floor. The applicant claimed that while the patient's bleeding had stopped by the time the colon was examined, the ability to directly visualize the entire colon using the Pure-Vu® System helped avoid a third CT angiography during this hospitalization and helped the physicians to confirm that prior coil embolization had not resulted in focal colonic ischemia. The applicant asserted that this case showed that the Pure-Vu® System can be used with minimal preparation, enabling rapid investigation of LGIB in a very complex patient. The applicant concluded that these case studies demonstrate that a change in patient management occurs when the option of the Pure-Vu® System is available, especially when there is an urgent or severe GI bleed, where circumstances where other procedures (such as CT angiography) are insufficient and the option to perform the colonoscopy sooner is preferred.

After reviewing the information submitted by the applicant as part of its FY 2022 new technology add-on payment application for the Pure-Vu® System, we have the following concerns. While the studies provided in support of the Pure-Vu® System measure improvement of bowel preparation using the BBPS, the applicant did not provide data indicating that the improved BBPS directly leads to improved clinical outcomes (for example, reduction of blood loss in LGIB or reduction of missed polyps) based on use of the Pure-Vu® System. Additionally, we note that the applicant has not provided any studies comparing the efficacy of the Pure-Vu® System to other existing methods or products for irrigation in support of its claims that the product is superior at removing debris from the colon while simultaneously preventing the colon from collapsing, allowing use of the working channel, or improving outcomes. Furthermore, we note that many of the provided studies were based on small sample sizes, which may affect the quality and reliability of the data provided in support of the technology. In addition, we note that the methodology described in the provided studies often involved time to adequately prepare the colon and included outpatient planned procedures, which may not reflect the emergent situations that the applicant states the Pure-Vu® System is intended to address in the inpatient setting. We also note that the Helmut, et al. study noted one procedure related perforation which required surgical repair and we invite public comments regarding the concern of procedure related perforation.

We are inviting public comments on whether the Pure-Vu® System meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the Pure-Vu® System.

o. Rapid ASPECTS

iSchemaView (which is in the process of a name change to RapidAI) submitted an application for new technology add-on payments for Rapid ASPECTS for FY 2022. According to the applicant, Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using computed tomography (CT) image data. The applicant asserted that the software automatically registers images and segments and analyzes ASPECTS Regions of Interest (ROIs). According to the applicant, Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The applicant stated that the imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT Score.

The applicant stated Rapid ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known Middle Cerebral Artery (MCA) or Internal Carotid Artery (ICA) occlusion, for evaluation of extent of disease. The applicant stated that extent of disease refers to the number of ASPECTS regions affected, which is reflected in the total score.

According to the applicant, the Rapid ASPECTS device provides information that may be useful in the

characterization of early ischemic brain tissue injury during image interpretation (within 6 hours). The applicant stated Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring. The applicant stated that Rapid ASPECTS is not intended for primary interpretation of CT images; it is used to assist physician evaluation. The applicant asserted Rapid ASPECTS has been validated in patients with known MCA or ICA occlusion prior to ASPECT scoring.

According to the applicant, when patients with a suspected stroke arrive at an emergency department, they are rapidly triaged to the CT scanner for a non-contrast CT (NCCT) and CT angiography (CTA). The applicant stated that CTA directly images large vessel occlusions and the NCCT can exclude brain hemorrhage and identify early signs of brain infarction. The applicant asserted that automated large vessel occlusion (LVO) detection software is now used at many sites to quickly identify LVOs on CTA and provide physicians with early notification that an LVO has been identified. The applicant stated that following identification of an LVO, the next imaging evaluation required is for a physician, typically a radiologist or neuroradiologist, to determine the ASPECT score by taking a close look at the NCCT for evidence of early infarct signs. The applicant stated that patients with an ASPECT score between 6 and 10 who meet clinical criteria for thrombectomy should receive thrombectomy as soon as possible, if treatment can occur within 6 hours of symptoms onset. The applicant asserted that for patients who present beyond 6 hours, a CT perfusion or MRI scan are required to identify which patients are eligible for thrombectomy.

The applicant stated approximately 800,000 primary (first-time) or secondary (recurrent) strokes occur each year in the U.S., with the majority being primary strokes (roughly 600,000). Of these strokes, approximately 87% are ischemic infarctions, 10% are primary hemorrhages, and 3% are subarachnoid hemorrhage.[520] According to the applicant, the incidence of stroke rapidly increases with age, doubling for each decade after age 55. The applicant asserted that among adults ages 35 to 44, the incidence of stroke is 30 to 120 in 100,000 per year, and for those ages 65 to 74, the incidence is 670 to 970 in 100,000 per year. Therefore, according to the applicant, the primary burden of stroke affects the Medicare-age population. The applicant stated the most disabling strokes are those due to large vessel occlusions (LVOs), and treatment of these strokes has the largest therapeutic benefits.[521]

The applicant stated that Rapid ASPECTS received FDA 510(k) clearance as a CADx software device on June 26, 2020 and provided a date of first installation of September 1, 2020. The applicant described Rapid ASPECTS as a machine learning-based automated software for assessment of ASPECTS. The applicant asserted that Rapid ASPECTS remains the only cleared ASPECTS software and the only stroke imaging software to receive a CADx clearance by the FDA. The legally marketed predicate device that Rapid ASPECTS is substantially equivalent to, per FDA, is QuantX,[522] which was granted De Novo authorization on July 19, 2017. QuantX is a CADx software device used to assist radiologists in the assessment and characterization of breast abnormalities using magnetic resonance (MR) image data and is indicated for evaluation of patients presenting for high-risk screening, diagnostic imaging workup, or evaluation of extent of known disease.[523]

We note the applicant submitted a request for approval of a unique ICD–10–PCS procedure code to identify use of the technology beginning FY 2022. According to the applicant, this new ICD–10–PCS code would be reported in addition to the non-contrast CT using the appropriate code as listed in current coding systems.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted Rapid ASPECTS uses a new mechanism of action (machine learning) to assess CT scans and synthesize a single ASPECT score when compared to existing options which are limited to clinical assessment by a human reader. According to the applicant, this software remains the only FDA-cleared ASPECTS software and the only stroke imaging software to receive a CADx clearance by the FDA. The applicant asserted Rapid ASPECTS is fully automated and produces a score for each of the 10 ASPECTS regions, as well as a total score in approximately 2 minutes.

With regard to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant stated that cases involving Rapid ASPECTS would be assigned to the same MS–DRGs as cases involving patients confirmed with an eligible LVO by a positive CTA. According to the applicant, in these cases, the traditional clinical pathway requires a physician to determine the ASPECT score through an imaging evaluation. The applicant noted that Rapid ASPECTS may result in patients being assigned to a different MS–DRG depending on whether or not a mechanical thrombectomy is performed as a result of the Rapid ASPECTS results.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted Rapid ASPECTS addresses the current stroke population.

In summary, the applicant believes that Rapid ASPECTS is not substantially similar to other currently available therapies because Rapid ASPECTS uses a new mechanism of action (machine learning) to assess CT scans and synthesize a single ASPECT score. We are unclear as to whether machine learning to assess CT scans and synthesize a single ASPECT score would represent a unique mechanism of action, or how the mechanism of action by which Rapid ASPECTS assesses stroke imaging is distinct from other automated stroke imaging analysis tools, or the traditional hospital workflow.

We continue to be interested in public comments regarding issues related to determining newness for technologies that use AI, an algorithm or software, as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58628). Specifically, we are interested in public comment on how these technologies, including devices classified as radiological computer aided triage and notification software and radiological computer-assisted diagnostic software, may be considered for the purpose of identifying a unique mechanism of

[520] Ovbiagele B, et al. Stroke Epidemiology: Advancing Our Understanding of Disease Mechanism and Therapy *Neurotherapeutics.* (2011) 8:319–329.

[521] Ovbiagele B, et al. Stroke Epidemiology: Advancing Our Understanding of Disease Mechanism and Therapy *Neurotherapeutics.* (2011) 8:319–329.

[522] Rapid ASPECTS 510(k) clearance letter from FDA: *https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200760.pdf.*

[523] QuantX De Novo decision summary from FDA: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170022.pdf.*

action; how updates to AI, an algorithm or software would affect an already approved technology or a competing technology; whether software changes for an already approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an already approved AI new technology.

We invite public comments on whether Rapid ASPECTS is substantially similar to existing technologies, including specifically with respect to the mechanism of action, and whether it meets the newness criterion.

With respect to the cost criterion, the applicant provided three analyses: (1) A baseline analysis containing all cases reporting one of the targeted ICD–10–CM codes below as the principal diagnosis code for cerebral infarction that map to one of the applicant's targeted MS–DRGs; (2) an analysis limited to MS–DRGs with a case volume over 100; and (3) an analysis limited to MS–DRGs 023, 062, 064, 065, and 066, which per the applicant would reflect 80 percent of all stays. For the baseline analysis, the applicant first extracted all inpatient stays from the CY 2018 Limited Data Set Standard Analytic File (LDS SAF) that contained a principal ICD–10–CM diagnosis code for cerebral infarction. The applicant used the following ICD–10–CM diagnosis codes.

An Inpatient Stay Must Have At Least One Of The Listed Cerebral Infarction Diagnosis Codes As A Principal Diagnosis Code To Be Included In The Analysis	
ICD-10-CM Code	**Description**
Cerebral Arteries	
I63.311	Cerebral infarction due to thrombosis of right middle cerebral artery
I63.312	Cerebral infarction due to thrombosis of left middle cerebral artery
I63.313	Cerebral infarction due to thrombosis of bilateral middle cerebral arteries
I63.319	Cerebral infarction due to thrombosis of unspecified middle cerebral artery (NOTE: Not a legitimate billing code)
I63.321	Cerebral infarction due to thrombosis of right anterior cerebral artery
I63.322	Cerebral infarction due to thrombosis of left anterior cerebral artery
I63.323	Cerebral infarction due to thrombosis of bilateral anterior cerebral arteries
I63.329	Cerebral infarction due to thrombosis of unspecified anterior cerebral artery (NOTE: Not a legitimate billing code)
I63.331	Cerebral infarction due to thrombosis of right posterior cerebral artery
I63.332	Cerebral infarction due to thrombosis of left posterior cerebral artery
I63.333	Cerebral infarction due to thrombosis of bilateral posterior cerebral arteries
I63.411	Cerebral infarction due to embolism of right middle cerebral artery
I63.412	Cerebral infarction due to embolism of left middle cerebral artery
I63.413	Cerebral infarction due to embolism of bilateral middle cerebral arteries
I63.421	Cerebral infarction due to embolism of right anterior cerebral artery
I63.422	Cerebral infarction due to embolism of left anterior cerebral artery
I63.423	Cerebral infarction due to embolism of bilateral anterior cerebral arteries
I63.431	Cerebral infarction due to embolism of right posterior cerebral artery
I63.432	Cerebral infarction due to embolism of left posterior cerebral artery
I63.433	Cerebral infarction due to embolism of bilateral posterior cerebral arteries
I63.442	Cerebral infarction due to embolism of left cerebellar artery
I63.511	Cerebral infarction due to unspecified occlusion or stenosis of right middle cerebral artery
I63.512	Cerebral infarction due to unspecified occlusion or stenosis of left middle cerebral artery
I63.513	Cerebral infarction due to unspecified occlusion or stenosis of bilateral middle cerebral arteries
I63.521	Cerebral infarction due to unspecified occlusion or stenosis of right anterior cerebral artery
I63.522	Cerebral infarction due to unspecified occlusion or stenosis of left anterior cerebral artery
I63.523	Cerebral infarction due to unspecified occlusion or stenosis of bilateral anterior cerebral arteries
I63.531	Cerebral infarction due to unspecified occlusion or stenosis of right posterior cerebral artery
I63.532	Cerebral infarction due to unspecified occlusion or stenosis of left posterior cerebral artery
I63.533	Cerebral infarction due to unspecified occlusion or stenosis of posterior cerebral arteries
I66.01	Occlusion and stenosis of right middle cerebral artery not resulting in cerebral infarction
I66.02	Occlusion and stenosis of left middle cerebral artery not resulting in cerebral infarction

I66.03	Occlusion and stenosis of bilateral middle cerebral arteries
I66.11	Occlusion and stenosis of right anterior cerebral artery not resulting in cerebral infarction
I66.12	Occlusion and stenosis of left anterior cerebral artery not resulting in cerebral infarction
I66.13	Occlusion and stenosis of bilateral anterior cerebral arteries not resulting in cerebral infarction
I66.21	Occlusion and stenosis of right posterior cerebral artery, not resulting in cerebral infarction
I66.22	Occlusion and stenosis of left posterior cerebral artery, not resulting in cerebral infarction
I66.23	Occlusion and stenosis of bilateral posterior cerebral arteries
I66.3	Occlusion and stenosis of cerebellar arteries not resulting in cerebral infarction not resulting in cerebral infarction
I66.8	Occlusion and stenosis of other cerebral arteries not resulting in cerebral infarction
I67.1	Cerebral aneurysm. Nonruptured
I67.2	Cerebral atherosclerosis

The applicant then removed cases for hospitals that are not paid under the IPPS. The applicant also removed inpatient stays and their assigned MS–DRGs from its analysis where the assigned MS–DRG met any of the following conditions: (1) The MS–DRG is for a part of the body not related to the head; (2) the MS–DRG is a psychiatric MS–DRG, alcohol-related MS–DRG, or a catchall MS–DRG; (3) the MS–DRG has a very small number of cases; or (4) the MS–DRG is unlikely to involve an LVO. The applicant identified 66,990 cases mapping to 27 MS–DRGs, as listed in the following table, in descending order by volume:

MS-DRG	MS-DRG Title
065	Intracranial Hemorrhage or Cerebral Infarction w CC or TPA in 24 Hrs
064	Intracranial Hemorrhage or Cerebral Infarction w MCC
023	Craniotomy w Major Device Implant or Acute CNS Pdx w MCC or Chemotherapy Implant or Epilepsy w Neurostimulator
066	Intracranial Hemorrhage or Cerebral Infarction w/o CC/MCC
062	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia w Thrombolytic Agent w CC
024	Cranio w Major Dev Impl/Acute Complex CNS Pdx w/o MCC
061	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia w Thrombolytic Agent w MCC
027	Craniotomy & Endovascular Intracranial Procedures w/o CC/MCC
026	Craniotomy & Endovascular Intracranial Procedures w CC
025	Craniotomy & Endovascular Intracranial Procedures w MCC
063	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia w Thrombolytic Agent w/o CC/ MCC
068	Nonspecific CVA & Precerebral Occlusion w/o Infarct w/o MCC
038	Extracranial Procedures w CC
003	Ecmo or Trach w MV >96 Hrs or Pdx Exc Face, Mouth & Neck w Maj O.R.
037	Extracranial Procedures w MCC
093	Other Disorders of Nervous System w/o CC/MCC
092	Other Disorders of Nervous System w CC
004	Trach w MV >96 Hrs or Pdx Exc Face, Mouth & Neck w/oMaj O.R.
091	Other Disorders of Nervous System w MCC
034	Carotid Artery Stent Procedure w MCC
035	Carotid Artery Stent Procedure w CC
039	Extracranial Procedures w/o CC/MCC
071	Nonspecific Cerebrovascular Disorders w CC
067	Nonspecific CVA & Precerebral Occlusion w/o Infarct w MCC
070	Nonspecific Cerebrovascular Disorders w MCC
036	Carotid Artery Stent Procedure w/o CC/MCC
072	Nonspecific Cerebrovascular Disorders w/o CC/MCC

The applicant then standardized the charges and applied the 2-year charge inflation factor of 13.2 percent used to adjust the outlier threshold determination (85 FR 59039). The applicant did not remove charges for prior technology, as the applicant believes Rapid ASPECTS does not eliminate or replace any prior technology or services. The applicant also noted that it did not remove charges related to the prior technology, as the applicant believes Rapid ASPECTS does not reduce costs during the inpatient stay.

The applicant then added charges for the technology. The applicant stated that it estimated the cost per case of Rapid ASPECTS using historical utilization data gathered from its Rapid CTA module. The applicant anticipates Rapid ASPECTS will be used in the same hospital sites as Rapid CTA, which also provides the applicant with a baseline number of Medicare and non-Medicare patients who were identified with a suspected LVO. The applicant estimated that approximately 20.5 percent of all patients who received a RAPID CTA scan qualified as inpatients eligible for a Rapid ASPECTS scan. The applicant divided the total number of qualified Medicare and non-Medicare inpatients by the total number of subscriber hospitals to arrive at an average number of inpatients eligible to be scanned with Rapid ASPECTS per subscriber hospital per year. The applicant then took the estimated average sales price per annual contract of Rapid ASPECTS per hospital and divided it across the estimated annual number of Rapid ASPECTS inpatients per site to estimate the average cost per case per subscriber hospital. Finally, the applicant divided the average cost per case by the national average CCR for radiology of 0.136 (85 FR 58601).

The applicant calculated a case-weighted threshold amount of $76,398 and a final inflated average case-weighted standardized charge per case of $90,097. Based on this analysis, the applicant asserted that Rapid ASPECTS meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the case-weighted threshold amount. The applicant submitted two additional scenarios to demonstrate that the technology meets the cost criterion using the same methodology described but with limits on the cases. The first scenario limited the analysis to MS–DRGs with at least 100 cases. This resulted in a case-weighted threshold of $76,457 and a final inflated average case weighted standardized charge per case of $90,172. The second scenario limited the analysis to MS–DRGs 023, 062, 064, 065, and 066, which per the applicant reflect 80 percent of all stays. This second alternative method resulted in a case-weighted threshold of $67,890 and a final inflated average case-weighted standardized charge per case of $77,614. Across all three analyses, the applicant maintained that the technology meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount.

We note the following concerns regarding the cost analysis for Rapid ASPECTS. The applicant stated it removed from its analysis those cases and their assigned MS–DRG where the assigned MS–DRG was for a body part that is not the head; however the list of MS–DRGs the applicant presented included MS–DRGs 37 (Extracranial Procedures w/MCC) and 38 (Extracranial Procedures w/CC), which by definition describe procedures outside of the head. We would like to understand why these MS–DRGs and their assigned cases were included in the baseline analysis. We would also like to understand the time period of the claims the applicant selected from the CY 2018 SAF, as this could have implications for the inflation factor used to update charges if the applicant selected claims from FY 2018 as opposed to FY 2019.

The applicant appears to have used a single list price of Rapid ASPECTS per hospital with a cost per patient that can vary based on the volume of cases. We note that the cost per patient varies based on the utilization of the technology by the hospitals. The cost per patient could be skewed by the small number of hospitals utilizing the technology and their low case volumes. It is possible, if hospitals with large patient populations adopt Rapid ASPECTS, the cost per patient would be significantly lower.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58630), we stated our understanding that there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We stated our intent to continue to consider the issues relating to the calculation of the cost per unit of technologies sold on a subscription basis as we gain more experience in this area. We continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We invite public comment on whether Rapid ASPECTS meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by improving accuracy of ASPECT scoring. The applicant also asserted it improves diagnostic decisions by reducing inter-rater variability of ASPECT scoring. The applicant also asserted it represents a substantial clinical improvement by improving treatment decisions and by improving time to treatment.

According to the applicant, the first stroke treatment, tissue plasminogen activator (tPA), was first approved in the United States for intravenous administration to patients with acute stroke in 1996, and a study demonstrating successful catheter-directed intra-arterial infusion of a thrombolytic agent for this indication was first published in 1999.[524] The applicant asserted that the first positive randomized controlled studies using modern mechanical thrombectomy devices for LVO stroke were published in 2015 and support combined treatment with tPA and catheter-based thrombectomy as the most effective treatment approach for patients who can be treated within six hours of symptom onset.[525] According to the applicant, following the publication of these trials, the American Heart Association (AHA) and American Stroke Association (ASA) released new guidelines in 2016, 2018 and 2019 that all specified the following Level 1A recommendation:

Patients should receive mechanical thrombectomy with a stent retriever if they meet all the following criteria:

- Pre-stroke modified Rankin Score (mRS) score of 0 to 1.
- Causative occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA) segment 1 (M1).
- Age ≥18 years.
- NIH Stroke Scale (NIHSS) score of ≥6.
- Alberta stroke program early CT score (ASPECTS) of ≥6.
- Treatment can be initiated (groin puncture) within 6 hours of symptom onset.[526]

According to the applicant, the above-recommended guidelines from the

[524] Furlan A, Higashida R, et al. Intra-arterial prourokinase for acute ischemic stroke: the PROACT II study: a randomized controlled trial: Prolyse in Acute Cerebral Thromboembolism. *JAMA.* 1999;282:2003–2011.

[525] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[526] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

AHA/ASA have been widely accepted and outline the key requirements that are still used today to select early window (less than 6 hours) candidates for thrombectomy. The applicant asserted the imaging requirements (the second and the fifth criterion) require that patients be screened for an LVO with CTA and then once an LVO in the ICA or MCA is discovered, the ASPECTS score must be assessed to verify that it is 6 or higher. According to the applicant, the ASPECTS score is an assessment of the CT scan in a stroke patient to determine if there is evidence of irreversible injury in ten different brain regions. The applicant stated that patients who have more than five regions that are already irreversibly injured are not candidates for thrombectomy.

According to the applicant, it is well validated in the stroke literature that faster treatment leads to better outcomes. The applicant stated that compared with the best medical therapy alone, in the first five positive LVO endovascular thrombectomy trials that were published in the *New England Journal of Medicine* and subsequently summarized in a pooled analysis by the HERMES group, thrombectomy was associated with improved outcomes when procedure start (arterial puncture) could be performed within the first 7.3 hours after symptom onset among patients meeting the brain imaging entry criteria for inclusion in these randomized trials.[527] The applicant asserted that within this period, functional outcomes were better the sooner after symptom onset that endovascular reperfusion was achieved, emphasizing the importance of programs to enhance patient awareness, out-of-hospital care, and in-hospital management to shorten symptom onset-to-treatment times. The applicant asserted that the magnitude of the association between time to treatment and outcome is clinically meaningful. According to the applicant, in patients with acute ischemic stroke due to LVO, among every 1000 patients achieving substantial endovascular reperfusion, for every 15-minutes faster emergency department door-to-reperfusion time, an estimated 39 patients would have a less-disabled outcome at 3 months, including 25 more who would achieve functional independence (mRS 0–2).[528] The applicant stated that in addition to faster time from emergency department door to reperfusion, faster time from brain imaging to reperfusion was associated with better 3-month functional outcomes.[529]

According to the applicant, the interpretation of early infarct signs in CT first became clinically important following the FDA approval of tPA for stroke treatment in 1996 because it was shown that the response to tPA could be predicted based on the degree of early brain injury that could be visualized on the CT scan. The applicant asserted it was clear that intravenous tPA could be harmful in patients with advanced early infarct signs because they had a high risk of intracranial hemorrhage. The applicant stated, however, only rough qualitative estimates of the degree of early infarct signs were performed. The applicant asserted stroke clinicians generally felt safe to give tPA if the early infarct signs were confined to less than one-third of the middle cerebral artery territory.[530]

According to the applicant, beginning in the 2000s, a more detailed and quantitative analysis of early infarct signs was proposed: The Alberta Stroke Program Early CT score (ASPECTS).[531] The applicant stated this score requires the evaluation of 10 pre-defined MCA vascular territories. The applicant asserted these individual regions are assessed for focal hypoattenuation of the cortex and in the basal ganglia, reduction of gray and white matter differentiation, and the loss of the insular ribbon sign. According to the applicant, ASPECTS is calculated by subtracting 1 point for each involved region; scores less than 6 typically signify patients with an irreversible large hemispheric infarction.[532]

According to the applicant, the ASPECTS evaluation became clinically essential in 2015 after mechanical thrombectomy was found to be effective for treatment of patients with a large vessel occlusion within the 6-hour time frame.[533] [534] The applicant stated that some of the large randomized controlled trials that ultimately led to the establishment of thrombectomy as a standard procedure required an ASPECTS greater than or equal to 6 for inclusion. According to the applicant, the MR CLEAN trial, which enrolled patients with lower ASPECT scores than the other four trials, reported the smallest overall treatment effect and in particular, patients with an ASPECT score less than 5 did not show benefit with an adjusted odds ratio close to 1.0.[535] The applicant asserted that for these reasons, an ASPECTS evaluation is required in most national and international thrombectomy guidelines. The applicant stated most guidelines, including the AHA/ASA guidelines discussed above, require an ASPECT score greater than or equal to six 6 for a patient to qualify for thrombectomy in the early treatment window.[536]

The applicant asserted ASPECT score determination is challenging because early infarct signs are often very subtle and challenging to interpret correctly. According to the applicant, there is often disagreement between experts on the exact score and sometimes these disagreements preclude a definite answer regarding if the patient qualifies for thrombectomy or not. The applicant asserted these interpretation challenges are manifested by limited inter-rater

[527] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[528] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[529] Ibid. Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[530] von Kummer R, Allen KL, Holle R, et al. Acute stroke: usefulness of early CT findings before thrombolytic therapy. *Radiology* 1997; 205:327–33.

[531] Barber PA, Demchuk AM, et al. Validity and reliability of a quantitative computed tomography score in predicting outcome of hyperacute stroke before thrombolytic therapy. ASPECTS Study Group. Alberta Stroke Programme Early CT Score. *Lancet.* 2000 May 13;355(9216):1670–4.

[532] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[533] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[534] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

[535] Berkhemer OA, Fransen PS, et al; MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med.* 2015;372:11–20.

[536] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

[537] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[538] Kobkitsuksakul C, Tritanon O, Suraratdecha V. Interobserver agreement between senior radiology resident, neuroradiology fellow, and experienced neuroradiologist in the rating of Alberta Stroke Program Early Computed Tomography Score (ASPECTS). *Diagn Interv Radiol.* 2018.

[539] McTaggart RA, Jovin TG, Lansberg MG, et al. Alberta stroke program early computed

agreement, even among experts.[537] [538] [539] The applicant cited the DEFUSE 2 study in which two expert readers graded ischemic change on NCCT using the ASPECT score. The applicant asserted that full-scale agreement (measured by the intraclass correlation coefficient) for CT–ASPECTS was only moderate at 0.579.[540] According to the applicant, these inter-rater differences can have important clinical implications, as discussed further. The applicant asserted that many physicians who evaluate acute stroke patients are not confident that they can accurately determine an ASPECT score, and oftentimes there are significant delays before a radiologist reads the scan.

The applicant stated current AHA/ASA guidelines recommend a CT scan be performed within 25 minutes of Emergency Department arrival and the radiologist interpretation of the scan occur within 45 minutes of arrival.[541] According to the applicant, based on these guidelines, radiologists have about 20 minutes to read the scan, however, many hospitals, especially community and primary stroke centers, do not meet these guidelines. The applicant asserted Medicare data indicate that only 72% of patients meet these guidelines. The applicant stated that automated software, such as Rapid ICH, Rapid LVO and Rapid ASPECTS can assess CT and CTA findings (both to rule out hemorrhage, confirm an LVO and to assess early signs of infarction with ASPECTS) within minutes.

According to the applicant, the limited inter-rater agreement for traditional ASPECT scoring can lead to triaging ineligible patients to thrombectomy or failing to treat eligible patients. The applicant cited a study in which four experienced readers rated ASPECT scores in patients who presented with LVO and severe strokes. The applicant stated the inter-rater agreement between these raters was poor with an interclass correlation of 0.32.[542] According to the applicant, the range of agreement for individual raters with the gold standard assessment of the score (obtained with a concurrent MRI) for identifying patients with a score less than six 6 ranged from 35% to 94%. The applicant asserted this study demonstrates there can be substantial disagreement between physicians regarding if a patient is eligible for thrombectomy based on their assessment of the ASPECT score, which can lead to eligible patients not receiving this highly effective therapy, as well as the performance of unnecessary procedures.

The applicant asserted that particularly the Medicare population might be at risk and impacted by these limitations as the majority of LVOs occur in the Medicare population. The applicant stated that the average age of patients in the HERMES pooled analysis of thrombectomy studies was 68 years.[543] Therefore, according to the applicant, inaccuracy of traditional ASPECT scoring translates into a substantial percentage of Medicare patients having erroneous triage decisions made regarding their eligibility for thrombectomy, which it asserted can result in unnecessary procedures and increased Medicare costs, as well as increased disability in eligible patients who are not treated because of inaccurate ASPECT scoring.

As stated previously, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by improving accuracy of ASPECT scoring. The applicant presented three retrospective cohort studies (two peer-reviewed and one under review) to support the claim that diagnostic decisions made by clinicians would have been improved with use of Rapid ASPECTS. According to the applicant, two of the studies showed that the automated Rapid ASPECTS score is significantly more accurate than the scores obtained by experienced clinicians.[544] [545]

The applicant submitted a retrospective cohort study which compared ASPECT scoring of CT images from patients with MCA occlusion (n=100) between Rapid ASPECTS software and two expert neuroradiologist reads. According to the applicant, Rapid ASPECTS showed a substantial agreement (k=0.78) when imaging took place more than 1 hour after symptom onset, which increased to high agreement (k=0.92) for imaging occurring after 4 hours. The applicant asserted that the neuroradiologist raters did not achieve comparable results to the software until the time interval of greater than 4 hours (k=0.83 and k=0.76). In this study, experts developed the reference consensus score and then, after 6 weeks, the same two neuroradiologists again determined ASPECTS by using only the baseline CT. The experts had moderate agreement with the consensus score (k=0.57 and k=0.57) while Rapid ASPECTS had better agreement (k=0.9). There was minimal agreement across experts and software in the timeframe of less than 1 hour between symptom onset and imaging, but better software agreement when the time was between 1 and 4 hours. There was agreement across experts for imaging occurring after 4 hours. According to the applicant, this study showed that in acute stroke of the MCA, Rapid ASPECTS had better agreement than that of human readers with a predefined consensus score.[546]

The applicant submitted another retrospective cohort study to compare Rapid ASPECTS, as well as the mean score from four experienced readers, with a diffusion-weighted magnetic resonance imaging (DW–MRI) ASPECTS obtained following the baseline CT in patients (n=65) with large hemispheric infarcts.[547] DW–MRI is sensitive in the detection of small and early infarcts. Small infarcts might not appear on CT scans for days. The AHA/ASA guidelines state that DW–MRI can be useful for selecting candidates for mechanical thrombectomy between 6 and 24 hours after the patient was last known well (that is, the time at which the patient was known to be without signs and symptoms of the current stroke).[548]

tomographic scoring performance in a series of patients undergoing computed tomography and MRI: Reader agreement, modality agreement, and outcome prediction. *Stroke.* 2015 Feb;46(2):407-12.

[540] McTaggart RA, Jovin TG, Lansberg MG, et al. Alberta stroke program early computed tomographic scoring performance in a series of patients undergoing computed tomography and MRI: Reader agreement, modality agreement, and outcome prediction. *Stroke* 2015 Feb;46(2):407-12.

[541] AHA/ASA. Target: Stroke Campaign Manual, published 2010. *http://www.strokeassociation.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308277.pdf.*

[542] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients with Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[543] Goyal M, Menon BK, et al for the HERMES collaborators. Endovascular thrombectomy after large-vessel ischaemic stroke: a meta-analysis of individual patient data from five randomised trials. *Lancet* 2016; 387: 1723–31.

[544] Maegerlein C, Fischer J, Mönch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. *Radiology* 2019; 291:141–148.

[545] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[546] Maegerlein C, Fischer J, Mönch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. *Radiology* 2019; 291:141–148.

[547] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[548] Powers WJ, Rabinstein A, Ackerson T, et al. Guidelines for the Early Management of Patients With Acute Ischemic Stroke: 2019 Update to the 2018 Guidelines for the Early Management of Acute Ischemic Stroke A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2019;50:e344–e418.

According to the applicant, Rapid ASPECTS' automated score had a higher level of agreement with the mean of the DW–MRI ASPECTS, both for the full scale and for the dichotomized scale of either <6 or ≥6 which is the difference for treatment/no treatment (difference in intraclass correlation coefficient, p<0.001). The applicant stated that the mean DW–MRI ASPECT score was <6 in 63/65 (97%) of the cases; of these, RAPID ASPECTS agreed with the DW–MRI score in 46/63 (73%) of the cases (95% confidence interval [CI] 60–83%) vs. 35/63 56% of the cases (95% CI 44–69%) for the median score of the two experienced readers (p=0.027). The range of agreement for individual clinician CT ASPECTS with the median DW–MRI score for identifying patients with a score <6 was 35% to 94%. According to the applicant, this study demonstrated the accuracy for determining which patients have an ASPECTS <6 (which would exclude them from thrombectomy) was significantly higher with the software.[549]

The applicant submitted an additional retrospective cohort study under review for publication which compared physicians' (two expert neuroradiologists and six typical readers) ability to read ASPECTS in patients with an LVO (n=50; 10 regions in each patients' scan for a total of 500 individual regions) within 6 hours of symptom onset when assisted by Rapid ASPECTS, compared with their unassisted score. The applicant stated that the average ASPECT score of three additional experienced neuroradiologists who were provided access to a follow-up MRI was used as the reference standard. The applicant asserted that when typical readers read the scan in conjunction with the Rapid ASPECTS software, their agreement with the expert reads improved from 72% to 78% (p<0.0001, test of proportions). According to the applicant, Rapid ASPECTS alone achieved correlations for total ASPECT scores that were similar to the three experienced neuroradiologist readers who had access to a follow-up MRI scan to help enhance the quality of their reads. The applicant asserted the results from this study showed that the aid of Rapid ASPECTS can significantly improve typical readers' scores and that the automated scores generated by Rapid ASPECTS are interchangeable with the scores generated by expert neuroradiologists.[550]

As stated previously, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement over existing technologies because it improves diagnostic decisions by reducing inter-rater variability of ASPECT scoring. To support this claim the applicant submitted the study performed by iSchemaView and analyzed by an independent statistician that led to the FDA clearance of Rapid ASPECTS. According to the applicant, acute CT scans in patients with LVO (n=50) were read by eight readers both with and without Rapid ASPECTS. The applicant asserted that the standard deviation of ASPECT scores ranged from 0.35 to 4.5 without assistance as compared to 0.46 to 4.7 with assistance. The applicant stated that the median standard deviation dropped from 2.2 to 1.4 when assistance was used to read the scans. According to the applicant, a t-test to evaluate the hypothesis of equal standard deviations supported a significant difference in standard deviations (p=0.0002), and non-parametric tests arrived at the same conclusion (p<0.0001 for a Wilcoxon Rank Sum Test).[551]

As stated previously, the applicant asserted Rapid ASPECTS represents a substantial clinical improvement by improving treatment decisions and by improving time to treatment. The applicant asserted that in the study performed by iSchemaView of the acute CT scans in patients with LVO (n=50) which were read by eight readers both with and without Rapid ASPECTS, a Receiver Operating Characteristic (ROC) analysis demonstrated significant improvement in typical readers' ability to identify patients who have a score of 6 to 10 if they read the scan in conjunction with the automated score. According to the applicant, the area under the curve (AUC) improved from 0.78 without Rapid ASPECTS to 0.85 with Rapid ASPECTS (p=0.0049).

The applicant asserted that of the 400 treatment assessments (50 scans * 8 readers) in this study, 7% were changed from an incorrect assessment to a correct assessment when the scan was read in conjunction with the automated score compared with traditional scoring, a statistically significant difference.[552]

The applicant cited three retrospective studies that, according to the applicant, have shown treatment decisions made by experienced clinicians would have been improved with the use of Rapid ASPECTS.[553] [554] [555] As stated previously, the applicant asserted that one study showed that agreement regarding whether a patient had a treatment-eligible score based on a concurrent MRI scan interpreted by two experts was significantly higher for the Rapid ASPECTS score than for experienced clinicians.[556] According to the applicant, Rapid ASPECTS has also been shown to improve the reads of a typical CT scan reader to become as accurate as a neuroradiologist read.[557] The applicant asserted that since radiologists are not immediately available at the time when many LVO patients present, and obtaining a read from a neuroradiologist often takes even longer, the time to determine an ASPECT score will be substantially improved with the software, leading to faster treatment times which have been shown to reduce disability. According to the applicant, Rapid ASPECTS provides an opportunity to impact the current selection and allocation pathway for stroke care.

After reviewing the information submitted by the applicant, we have the following questions regarding whether Rapid ASPECTS meets the substantial clinical improvement criterion.

In the studies provided by the applicant, the reference ASPECT score to which Rapid ASPECTS was compared was generally derived from a mean value of the ASPECT scores rated from a small sample of expert radiologists. We note that the radiologists used to identify the reference to which Rapid ASPECTS was compared may not be representative of radiologists in the United States. We are also unclear whether a mean ASPECT score, identified from radiologists whom

[549] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[550] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

[551] Copeland K. Variability of ASPECT Scores Internal Analysis iSchemaView of data submitted to U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health, 2020a.

[552] Copeland K. Treat/No Treat Analysis, Internal Analysis iSchemaView of data submitted to U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health, 2020.

[553] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[554] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

[555] Maegerlein C, Fischer J, Mönch S, MD et al. Automated Calculation of the Alberta Stroke Program Early CT Score: Feasibility and Reliability. *Radiology* 2019; 291:141–148.

[556] Albers GW, MD, Wald MJ, Mlynash M, et al. Automated Calculation of Alberta Stroke Program Early CT Score Validation in Patients With Large Hemispheric Infarct. *Stroke.* 2019;50:3277–3279.

[557] Delio PR, Wong ML, Tsai JP, et al. Assistance from Automated ASPECTS Software Improves Reader Performance (under review 2020).

the applicant describes as having low levels of agreement, is representative of a meaningful value as it does not represent the score of any particular radiologist. We further question whether individuals participating in these studies may have altered their behavior in a substantive way by interacting with computer-generated ratings, which would complicate study findings.

We further note that the correlation between the ASPECT scoring of expert and Rapid ASPECTS is the primary outcome in many of the articles provided. Though this information may be important and informative, it is not clear that a high correlation between expert and Rapid ASPECTS scoring is necessarily indicative of substantial clinical improvement. Furthermore, whether these providers agree with the technology does not determine whether they are correct, and it could be the case that both AI and radiologists agree on an incorrect score.

We note that the applicant stated that inter-rater disagreement with ASPECT scores leads to erroneous triage and treatment of Medicare patients. It is unclear how the applicant determined that disagreement between scores translates into inappropriate treatment, or necessarily shows that the scoring class (<6 vs ≥6) was inaccurate. The applicant also asserted that many physicians who evaluate acute stroke patients are not confident that they can accurately determine an ASPECT score, but it did not provide evidence to support this claim. Additionally, we observe that the studies provided did not demonstrate improvements in clinical outcomes such as disability, mortality, or length of stay; rather, improved outcomes were inferred by relying on the assumption that faster treatment results in better outcomes. Without measuring the impact of the technology on treatment outcomes, we are uncertain whether Rapid ASPECTS represents a substantial clinical improvement.

Lastly, we note that the applicant submitted the AHA/ASA guidelines and a review of stroke literature as support for clinical improvement. It is unclear how the guidelines support a finding of substantial clinical improvement for Rapid ASPECTS because the guidelines are for the current standard of care. Additionally, the applicant did not provide evidence to support its assertion that hospitals are not meeting the AHA/ASA guideline that radiologists read the CT scan of acute ischemic stroke patients within 20 minutes. The stroke literature review identified the inter-rater differences among ASPECT scoring, but did not demonstrate that inter-rater disagreements have led to triaging ineligible patients to thrombectomy or failing to treat eligible patients in clinical practice. It is unclear how the literature on inter-rater reliability for ASPECT scoring would demonstrate a substantial clinical improvement in how Rapid ASPECTS supports improved triaging of stroke care. The applicant's stroke literature review also identified that faster treatment leads to better outcomes. While this supports the urgency of stroke care, we are unsure how it demonstrates a substantial clinical improvement in how Rapid ASPECTS supports the urgency of stroke care.

We are inviting public comments on whether Rapid ASPECTS meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Rapid ASPECTS.

Comment: Several commenters, some of whom participated in one of the retrospective studies assessing Rapid ASPECTS, asserted that Rapid ASPECTS offers a substantial clinical improvement over the current standard of care for evaluation and treatment of patients diagnosed with LVO. They cited the studies summarized in this section and their clinical experience with Rapid ASPECTS and stated that Rapid ASPECTS improves treatment decisions by improving the accuracy of the assessment of candidates eligible for thrombectomy as well as reducing the time to appropriate treatment, which leads to better outcomes.

Response: We thank the commenters for their input and will take this information into consideration when deciding whether to approve new technology add-on payments for Rapid ASPECTS.

Comment: The applicant responded to the questions received at the New Technology Town Hall Meeting held in December 2020.

First, the applicant was asked if an ROC analysis had been performed with Rapid ASPECTS. The applicant stated that an ROC analysis had been performed for one of the retrospective studies assessing Rapid ASPECTS (Delio et al., 2020, under review). According to the applicant, using the scores for the 500 ASPECT regions for all 8 readers shows the AUC improved from 0.78 without RAPID to 0.85 with RAPID-assisted reads. The applicant stated the reference standard was the read from three experienced neuroradiologists who were provided access to a follow-up MRI scan to help enhance the accurary of the reference standard. The applicant asserted that the difference of 0.06 between the AUCs is statistically significant (p=0.0049).

Second, the applicant was asked if clinical benefits of RAPID Aspects were directly observed in prospective studies using the Rapid ASPECTS software. The applicant cited a recent retrospective study reporting a series of 176 patients from one hospital in Alexandria, Egypt diagnosed with Acute Ischemic Stroke (AIS) and subsequently treated with tPA between January 2018 and December 2019. Results were reported on 122 of these patients; 36 had their NCCT images analyzed by Rapid ASPECTS and 86 had their NCCT images analyzed by a remote neuroradiologist who received the image by the text messaging platform WhatsApp. The applicant asserted that Rapid ASPECTS had excellent agreement (k=0.80) with the neuroradiologist's read. The door-to-needle time for the 86 WhatsApp-read patients was 52.3 ±16 minutes and for the 36 Rapid ASPECTS patients was 36.8 ±11 minutes (p=0.001), representing a 14-minute reduction in the door-to-treatment time in Rapid ASPECTS group compared with the WhatsApp standard care group. According to the applicant, there was also a significantly increased likelihood of functional independence and fewer hemorrhagic complications in patients treated with reperfusion therapy in the Rapid ASPECTS group (p<0.001). The applicant also asserted that the use of Rapid ASPECTS was shown to be cost-effective in this study.[558]

Response: We appreciate the applicant's responses to questions asked at the New Technology Town Hall Meeting. Regarding generalizability, we note that the study results from a small, non-randomized sample generated from a single hospital in Alexandria, Egypt, may limit the ability to assert findings are generalizable across the variety of health care settings in the United States. We question whether the fact that the radiologists in this study received the images via WhatsApp is generalizable to the standard of care in the United States. We also note the study did not attempt to control for other variables such as the mix of patients in each group or time of day or other changes

[558] Mansour, Ossama Yassin, et al. ''Deciding Thrombolysis in AIS Based on Automated versus on WhatsApp Interpreted ASPECTS, a Reliability and Cost-Effectiveness Analysis in Developing System of Care.'' *Frontiers in Neurology* 11 (2020): 333.

in hospital practices over time. Additionally, since only patients with confirmed acute ischemic stroke were included in the study results, no information was given about the imaging and interpretation of other patients imaged. We note that the retrospective study had two neuroradiologists interpret the NCCT images at a later time and compare their ASPECT score to the Rapid ASPECTS-generated score reading the same scans. The study reported that in only one patient, the Rapid ASPECTS software underestimated the extent of early ischemic changes by providing an automated ASPECTS >6, while the score was <6 by agreement read (which would indicate that tPA treatment was not appropriate). We note that the clinical outcome of that patient was not reported.

We appreciate the information provided by the applicant and will take these comments into consideration when deciding whether to approve new technology add-on payments for Rapid ASPECTS.

p. Steripath® Micro™ Blood Collection System

Magnolia Medical Technologies, Inc. submitted an application for new technology add-on payments for the Steripath® Micro™ Blood Collection System, which is also referred to as the Steripath® Micro™ Initial Specimen Diversion Device (ISDD®), for FY 2022. The applicant described the Steripath® Micro™ ISDD® (''Steripath Micro'') as a proprietary and patent-protected single-use, disposable device, which is indicated for use in the collection of blood cultures by nurses, phlebotomists, and technicians in emergency departments and inpatient units in acute care hospitals to reduce blood culture contamination and false positive diagnostic test results for sepsis. According to the applicant, Steripath® Micro™ ISDD®, along with the Steripath and Steripath® Gen2, are part of a product portfolio utilizing their Steripath® ISSD® technology.

The applicant explained that the Steripath® Micro™ ISDD® uses a syringe-driven (or blood culture bottle-driven) architecture that uses negative pressure to flip a proprietary internal bladder, which, in turn, creates gentle negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood, the portion known to most likely contain contaminants. According to the applicant, once diversion is complete, the user presses a side button to isolate the diverted blood. The applicant further explained that once the blood is isolated, a second independent blood flow pathway is opened to collect the blood specimen into the syringe (or blood culture bottle) for blood culture testing.

The applicant stated that the design and development of the Steripath® Micro™ ISDD® was inspired by patients who present with symptoms concerning for sepsis and who are hypotensive (low blood pressure) and hypovolemic (low blood volume), have difficult intravenous access (DIVA), or are small in stature with lower blood volume. According to the applicant, clinicians typically utilize a syringe technique to collect blood from this patient population to enable management of negative pressure (attempting to avoid vein collapse) while improving the opportunity to collect a sufficient volume of blood to culture, which the applicant stated is a critical determinant of blood culture sensitivity (that is, avoiding false negative results). The applicant claimed that this patient population is generally ineligible for existing ISDD® technologies due to risk of vein collapse. According to the applicant, the negative pressure created by Steripath® Micro™ ISDD®'s bladder-driven mechanism is designed to achieve initial specimen diversion while avoiding collapsing of the veins (losing venous access) of this patient population. The applicant stated that the Steripath® Micro™ ISDD® is available with a preassembled sterile integrated syringe for syringe-driven diversion and blood culture sample collection, and components of the system may be used for infusion following sample collection after disconnection of the ISDD®.

According to the applicant, blood culture is the gold standard diagnostic test for bloodstream infections, including septicemia. The applicant explained that blood cultures are drawn from patients displaying symptoms of a potential bloodstream infection with results guiding therapeutic decisions and influencing outcomes for patients for their duration in acute care. The applicant stated that the standard of care is to collect two separate blood cultures, each consisting of two blood culture bottles containing aerobic or anaerobic medium. The applicant further noted that the major automated microbial blood culture detection systems (BACTEC and BacT/ALERT) recommend 8–10 mL of blood in each of the aerobic and anaerobic bottles—up to 40 mL total distributed across all four bottles.

The applicant stated that despite the critical role blood culture plays in providing diagnoses, an estimated 20 percent to over 50 percent of all positive blood culture results for sepsis are suspected to be false positive due to blood culture contamination, as explained in greater detail below.[559] The applicant stated that blood culture contamination creates clinical confusion which leads to a risk of inappropriate antibiotic therapy,[560 561 562 563] extended length of stay of an average of 2.0 to 2.4 days,[564 565] *Clostridium difficile* (CDI) infection,[566 567] multidrug resistance organism (MDRO) infections, Acute Kidney Injury (AKI),[568] hospital-acquired infection (HAI) or hospital-acquired condition (HAC),[569] false-positive Central Line-Associated Blood Stream Infection (CLABSI) treatment, false positives reported to National Healthcare Safety Network (NHSN)/CMS (thus biasing the data), and additional lab and/or other diagnostic testing.[570]

[559] Snyder S, et al. Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis. *Clinical Biochemistry.* 2012; 45(0):999–1011.

[560] Rupp M, et al. Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device. *Clinical Infectious Diseases.* 2017; 65(2):201–205.

[561] Bell M, et al. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. Journal of Emergency Nursing 44.6 (2018): 570–575.

[562] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. Clinical Microbiology Reviews. 2020; 33:e00009–19.

[563] Chang D, et al. Impact of blood culture diversion device on molecular pathogen identification on vancomycin use. Poster presented at: Society for Healthcare Epidemiology of America (2017).

[564] Skoglund E et al. Estimated Clinical and Economic Impact through Use of a Novel Blood Collection Device To Reduce Blood Culture Contamination in the Emergency Department: A Cost-Benefit Analysis. 2019; 57:e01015–18.

[565] Geisler B, et al. Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures oneconomic and clinical outcomes. *Journal of Hospital Infection.* 2019; 102:438–444.

[566] Ibid. Geisler B, et al. Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures oneconomic and clinical outcomes. *Journal of Hospital Infection.* 2019; 102:438–444.

[567] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. Clinical Microbiology Reviews. 2020; 33:e00009–19.

[568] Khalili H, et al. ''Antibiotics induced acute kidney injury: Incidence, risk factors, onset time and outcome.'' Acta Medica Iranica (2013): 51(12): 871–878.

[569] Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the Problem. *Clinical Microbiology Reviews.* 2020; 33:e00009–19.

[570] Ibid. Doern G, et al. A Comprehensive Update on the Problem of Blood Culture Contamination and a Discussion of Methods for Addressing the

The applicant explained that the detection of bacteremia is of particular concern for Medicare beneficiaries, given that the mean age for United States patients afflicted with sepsis in 2014 was 66.5, with sepsis present in 35 percent of all United States hospitalizations that resulted in death.[571]

With regard to the newness criterion, the Steripath® Micro™ ISDD® is a Class II medical device that received 510(k) clearance from the FDA on October 8, 2020. The 510(k) clearance was based on substantial equivalence to an earlier version of the device, Steripath® Gen2, which received 510(k) clearance on February 28, 2020. According to the applicant, the Steripath® ISDD® product portfolio, including the Steripath® Micro™ ISDD®, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination.[572] According to the applicant, a supplemental Special 510(k) submission and clearance is anticipated for an additional configuration of the Steripath® Micro™ ISDD® device that incorporates a butterfly safety venipuncture needle.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the use of the Steripath® Micro™ ISDD®. The applicant submitted a request for a new ICD–10–PCS procedure code for implementation on October 1, 2021.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

According to the applicant, diversion techniques use the same basic principle to reduce blood culture contamination by sequestering blood most likely to contain dislodged skin fragments and/or flora. With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the applicant discussed current/alternative treatments to avoid blood contamination, but states that manual diversion, passive diversion, and the Steripath® Gen2 device are not comparable alternatives to Steripath® Micro™.

According to the applicant, manual diversion, which involves the phlebotomist or other medical professional first collecting blood into a waste tube and then manually switching to a sample collection tube, is not a replacement for Steripath® Micro™ ISDD® because manual diversion inherently entails additional opportunities for human error through touch contamination and process variation, without the ability to manage and ensure healthcare worker compliance. The applicant further explained that manual diversion techniques introduce, at a minimum, one additional surface (waste tube top), which must either be sterilized (or carefully handled if pre-packaged sterile) to avoid cross contamination through the inoculation needle. The applicant noted that if the inoculation needle is contaminated in this manner, both blood culture bottles can become contaminated, which can be interpreted (inaccurately) as a true positive through laboratory testing. The applicant explained that Steripath® Micro™ ISDD® is a closed system to prevent opportunities for touch contamination beyond conventional methods of blood culture sample acquisition. The applicant further explained that since Steripath® Micro™ ISDD® is a pre-assembled and packaged sterile kit that does not require manual connections, it avoids touch-point contamination and prevents the need for additional time, focus, and manual diversion procedural compliance from the operator.

The applicant stated that the Kurin product, a competitor diversion device that uses passive diversion (or relying on the patients blood pressure), is not a comparable alternative to Steripath® Micro™ ISDD® as it is not FDA-cleared to reduce blood-culture contamination. The applicant claimed that passive diversion, because of its limitations, is integrated into the Kurin product to redirect 0.15 mL of blood. The applicant stated that passive devices are susceptible to bypassing diversion when the culture bottle is inoculated before diversion is complete, and that this limitation is not present within the Steripath® Micro™ ISDD® architecture. The applicant asserted that the Steripath® Micro™ ISDD® uses a novel syringe-driven (or blood culture bottle-driven) negative pressure to flip an internal bladder which, in turn, creates gentle negative pressure to divert and sequester the initial 0.6 to 0.9 mL of blood.

The applicant further stated that the Steripath® Gen2 ISDD® is not a comparable product to Steripath® Micro™ ISDD®, as it uses greater negative pressure to divert an initial 1.5–2.0 mL of blood for the adult patient population. According to the applicant, the Steripath® Micro™ ISDD® platform leverages ISDD® technology but is smaller, easier-to-use, and employs a novel proprietary diversion bladder technology to address patients who are hypotensive and hypovolemic, have difficult intravenous access, or are small in stature with lower blood volume.

Specifically, the applicant explained that the Steripath® Micro™ ISDD® uses syringe-driven (or blood culture bottle-driven) negative pressure to flip an internal bladder which in turn creates gentle negative pressure to effectively and consistently divert and sequester the initial 0.6 to 0.9 mL of blood, the portion known to most likely contain contaminants, with this patient population. The applicant asserts this differentiates the Steripath® Micro™ from the Steripath® Gen2. The applicant further explained that once diversion is complete, the user presses a button to isolate the diverted blood and, automatically, a second independent blood flow pathway opens to collect the blood specimen into the syringe (or blood culture bottle) for culture.

With respect to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant did not indicate whether the Steripath® Micro™ ISDD® would be assigned to the same MS–DRGs as cases representing patients who receive diagnostic information from competing technologies or traditional blood collection methods.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that the Steripath® Micro™ ISDD® was fundamentally designed to address a specific and broader patient population than any other technology that is currently available and FDA 510(k) cleared to prevent blood culture contamination. The applicant explained that in a certain subset of 'hard-stick' (low blood volume, hypovolemic and hypotensive) patients, blood culture using passive diversion or the Steripath® Gen2 ISDD® is not possible. According to the applicant, Steripath® Micro™ is the first ISDD designed specifically to address the unmet needs of the low blood volume, hypovolemic and hypotensive, 'hard-stick' patient populations (many requiring integrated sterile syringe collection) that is FDA 510(k) cleared indicated to reduce blood culture contamination.

We have the following concerns regarding whether the technology meets

Problem. *Clinical Microbiology Reviews.* 2020; 33:e00009–19.

[571] Rhee C, et al. Incidence and Trends of Sepsis in US Hospitals Using Clinical vs Claims Data, 2009–2014. *JAMA.* 2017; 318:1241–1249.

[572] Bell, Mary, et al. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. *Journal of Emergency Nursing* 44.6 (2018): 570–575.

the substantial similarity criteria and whether it should be considered new. Although we understand that the Steripath® Micro™ ISDD® version may divert less blood volume and utilize less negative pressure than the Steripath® Gen2 ISDD®, we note that both devices utilize negative pressure and, according to the applicant, leveraged Magnolia Medical Technologies' foundational ISDD® technology, and it is unclear whether this represents a new mechanism of action. We further note that the applicant also appears to consider the devices as similar, as they exclusively rely on studies conducted using the Steripath® Gen2 ISDD® to demonstrate substantial clinical improvement. We therefore believe that the newness date for Steripath® Micro™ ISDD® would begin on February 28, 2020, the date on which the predicate device received 510(k) clearance.

We also note that the applicant claimed that the Steripath® ISDD® product portfolio, including the Steripath® Micro™ ISDD®, is the only FDA 510(k)-cleared family of devices indicated to reduce blood culture contamination and we are inviting public comment on whether there are other FDA-cleared products designed to reduce blood culture contamination.

We are inviting public comments on whether the Steripath® Micro™ ISDD® is substantially similar to other technologies and whether the Steripath® Micro™ ISDD® meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR FR claims data file with the FY 2019 Final Rule IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using Steripath® Micro™ ISDD®.

The applicant used 37 Infection ICD–10–CM Diagnosis Codes and 15 Sepsis ICD–10–CM Diagnosis codes to identify patients who could potentially benefit from the Steripath® Micro™ ISDD® during an inpatient stay. These ICD–10–CM codes are provided in the following table:

BILLING CODE 4120–01–P

	37 Infection ICD-10-CM Diagnosis Codes
Code	**Code Descriptor**
A04.0	Enteropathogenic Escherichia coli infection
A04.1	Enterotoxigenic Escherichia coli infection
A04.2	Enteroinvasive Escherichia coli infection
A04.3	Enterohemorrhagic Escherichia coli infection
A04.4	Other intestinal Escherichia coli infections
A24.9	Melioidosis, unspecified
A49.01	Methicillin susceptible Staphylococcus aureus infection, unspecified site
A49.02	Methicillin resistant Staphylococcus aureus infection, unspecified site
A49.9	Bacterial infection, unspecified
B95.2	Enterococcus as the cause of diseases classified elsewhere
B95.61	Methicillin susceptible Staphylococcus aureus infection as the cause of diseases classified elsewhere
B95.62	Methicillin resistant Staphylococcus aureus infection as the cause of diseases classified elsewhere
B95.7	Other staphylococcus as the cause of diseases classified elsewhere
B96.1	Klebsiella pneumoniae [K. pneumoniae] as the cause of diseases classified elsewhere
B96.20	Unspecified Escherichia coli [E. coli] as the cause of diseases classified elsewhere
B96.21	Shiga toxin-producing Escherichia coli [E. coli] (STEC) O157 as the cause of diseases classified elsewhere
B96.22	Other specified Shiga toxin-producing Escherichia coli [E. coli] (STEC) as the cause of diseases classified elsewhere
B96.29	Other Escherichia coli [E. coli] as the cause of diseases classified elsewhere
B96.5	Pseudomonas (aeruginosa) (mallei) (pseudomallei) as the cause of diseases classified elsewhere
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomonas
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
J15.5	Pneumonia due to Escherichia coli
J15.6	Pneumonia due to other Gram-negative bacteria
J95.851	Ventilator associated pneumonia
K55.30	Necrotizing enterocolitis, unspecified
K55.31	Stage 1 necrotizing enterocolitis
K55.32	Stage 2 necrotizing enterocolitis
K55.33	Stage 3 necrotizing enterocolitis
N39.0	Urinary tract infection, site not specified
R78.81	Bacteremia
T81.4XXA	Infection following a procedure, initial encounter
Z22.321	Carrier or suspected carrier of Methicillin susceptible Staphylococcus aureus
Z22.322	Carrier or suspected carrier of Methicillin resistant Staphylococcus aureus
Z86.14	Personal history of Methicillin resistant Staphylococcus aureus infection

	15 Sepsis ICD-10-CM Diagnosis codes
Code	Code Descriptor
A26.7	Erysipelothrix sepsis
A32.7	Listerial sepsis
A41.01	Sepsis due to Methicillin susceptible Staphylococcus aureus
A41.02	Sepsis due to Methicillin resistant Staphylococcus aureus
A41.1	Sepsis due to other specified staphylococcus
A41.2	Sepsis due to unspecified staphylococcus
A41.50	Gram-negative sepsis, unspecified
A41.51	Sepsis due to Escherichia coli [E. coli]
A41.52	Sepsis due to Pseudomonas
A41.59	Other Gram-negative sepsis
A41.81	Sepsis due to Enterococcus
A41.89	Other specified sepsis

	15 Sepsis ICD-10-CM Diagnosis codes
Code	Code Descriptor
A41.9	Sepsis, unspecified organism
R65.20	Severe sepsis without septic shock
R65.21	Severe sepsis with septic shock

BILLING CODE 4120–01–C

In its analysis, the applicant identified a primary cohort to assess whether this therapy met the cost criterion. The applicant stated that clinical literature suggests the DIVA population represents anywhere from 17 percent to 59 percent of all patients that present as symptomatic for sepsis and require blood cultures.[573] [574] [575] The applicant added that the literature did not provide any additional information on the distribution of the DIVA population within the larger infection/sepsis population. To account for this, the applicant randomly selected 33% of claims that included one of the ICD–10 codes listed above in one of the first two diagnosis code positions on the claim to include in the cost analysis.

The applicant removed MS–DRGs describing kidney and urinary tract infections and renal failure because these cases are not likely to benefit from use of the Steripath® Micro™ ISDD®. The applicant stated that these diagnoses rely on technologies not relevant to Steripath® Micro™ ISDD®, such as urine cultures and blood cultures specific to urea and creatinine. Lastly the applicant excluded cases in MS–DRGs that accounted for less than 1% of the total cases in the identified sample.

The claim search conducted by the applicant resulted in 295,790 claims mapping to six MS–DRGs: 871 (Septicemia or severe sepsis w/o mv >96 hours w mcc), 872 (Septicemia or severe sepsis w/o mv >96 hours w/o mcc), 853 (Infectious & parasitic diseases w o.r. procedure w mcc), 870 (Septicemia or severe sepsis w mv >96 hours or peripheral extracorporeal membrane oxygenation (ecmo)), 854 (Infectious & parasitic diseases w o.r. procedure w cc), and 177 (Respiratory infections & inflammations w mcc). The applicant determined an average unstandardized case weighted charge per case of $69,973.

The applicant stated that studies show blood culture contamination (BCC) increases length of stay (LOS) and leads to unnecessary antimicrobial therapy and/or hospital-acquired conditions. The applicant stated that a retrospective analysis involving hospitalized patients with septicemia-compatible symptoms found that avoiding BCC would decrease costs by $6,463, including $4,818 in savings for inpatient care. 53 percent of savings were attributed to reduced LOS and 26 percent to reduced antibiotic use.[576] The applicant stated that to account for these savings, they removed $2,500 by inflating costs to charges using the national average cost-to-charge ratio (CCR) for routine days and $2,300 by inflating costs to charges using the pharmacy national average CCR. Because the previous study cited did not describe where non-LOS related inpatient savings arose, the applicant assumed that the savings arose from reduced drug use and therefore the pharmacy national average CCR was used.

Because, according to the applicant, savings accrue in around 3% of cases where the Steripath® Micro™ ISDD® is used, the applicant applied three percent of the savings described above to every case in the sample population. The applicant stated that removing the $4,800 in cost savings from 3 percent of the cases is mathematically the same as removing 3 percent of the cost savings from all cases. The applicant then standardized the charges using the FY 2019 Final Rule Impact File. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). To calculate the charges for the technology, the applicant used the national average CCR for the Supplies and Equipment cost center of 0.297 from the FY 2021 Final IPPS rule. The applicant calculated a final inflated average case-

[573] Sou, V., et al. A clinical pathway for the management of difficult venous access. BMC Nursing 16, 64 (2017).

[574] Armenteros-Yeguas V., et al. Prevalence of difficult venous access and associated risk factors in highly complex hospitalized patients. J Clin Nurs. 2017;26(23–24):4267–4275.

[575] Van Loon, FH, et al. Development of the A–DIVA Scale: A Clinical Predictive Scale to Identify Difficult Intravenous Access in Adult Patients Based on Clinical Observations. Medicine. 2016 Apr;95(16)e3428.

[576] Geisler, BP, *et al.* Model to evaluate the impact of hospital-based interventions targeting false-positive blood cultures on economical and clinical outcomes. J Hosp Infect. 2019 Aug;102(4):438–444.

weighted standardized charge per case of $76,796, which exceeded the average case-weighted threshold amount of $69,973 by $6,824. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

Based on the information provided by the applicant, we note the following concerns with regard to the cost criterion. In its analysis, the applicant stated it randomly selected 33% of claims that included one of the ICD–10 codes listed above in one of the first two diagnosis code positions on the claim to include in the cost analysis. Implicit in this decision to randomly select a subsample is the belief that Steripath® Micro™ ISDD® cases are randomly distributed across all cases identified. If performed properly, the intent of random sampling from a population is to identify a smaller group of cases which remains representative or similar to the greater population. An added effect of proper random sampling is that the sample often has less variance than the population from which it was drawn. We are therefore concerned that random sampling may be inappropriate in this situation if the potential cases are not similarly randomly distributed.

Furthermore, if it is true that a subset of cases would be more representive of cases eligible for use of the Steripath® Micro ™ ISDD®, it may be more likely that those cases will be distributed based on certain characteristics, not randomly distributed. We are seeking public comment on whether the random sample used by the applicant would appropriately identify the cases eligible for the use of Steripath.

In its cost analysis, the applicant stated that, in order to account for savings from the use of Steripath® Micro™ ISDD®, it removed $2,500 by inflating costs to charges using the national average cost-to-charge ratio (CCR) for routine days and $2,300 by inflating costs to charges using the pharmacy national average CCR. From a methodological standpoint, we are not certain that the data from which savings were calculated are generalizable to the broader Medicare population's experience if Steripath® Micro™ Blood Collection System is used. Specifically, we are not certain that the patient population and the resulting conclusions from the aforementioned study [577] adequately generalize to the Medicare population.

Lastly, the applicant stated that because savings accrue in around three percent of cases where the Steripath® Micro™ ISDD® is used, the applicant applied three percent of the savings described previously to every case in its sample population. We are unclear whether the three percent of cases which experienced savings in the one study provided by the applicant is adequately representative of the Medicare population. We are not certain that three percent of a sample experiencing some level of savings is the same as all cases experiencing three percent savings. Therefore, we are not certain that it is appropriate to apply three percent of savings across all cases in the applicant's cost analysis. As with the reduction in charges discussed previously, while the applicant's approach provides a more conservative estimate for purposes of the cost criterion, we question whether it accurately reflects the experiences of providers and Medicare beneficiaries.

We invite public comment on whether Steripath® Micro™ ISDD® meets the cost criterion. With respect to the substantial clinical improvement criterion, the applicant asserted that the Steripath® Micro™ ISDD® represents a substantial clinical improvement over existing technologies. The applicant stated that data from studies show that Steripath Micro™ ISDD® offers the ability to reduce blood collection contamination with skin flora and asserted that it improves clinical outcomes relative to services or technologies previously available as demonstrated by reducing clinically significant adverse events (that is, a decrease in inappropriate antibiotic use and a decrease in inappropriate hospitalizations).

The applicant submitted with its application 17 Steripath® ISDD® technology-specific studies, including 5 peer-reviewed studies published in scientific journals, that it stated support the contamination rate reduction with Steripath® Gen2 ISDD ® of 73.6 percent to 100 percent, with resulting sustained contamination rates of 0.97 percent to 0.0 percent, which the applicant stated is below the 3.0 percent gold standard benchmark rate for blood culture contamination.[578]

The applicant submitted a retrospective controlled study by Bell M, et al.[579] that showed that investigators seeking to lower the blood culture contamination rate at four different Lee Health (a healthcare system in Florida) emergency departments found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 83.0 percent when compared to conventional methods of sample acquisition, (that is without diversion). The Lee Health emergency departments compared contamination rates obtained using Steripath® Gen2 ISDD® device as the standard of care from May 2016 through November 2016 to conventional methods which were collected from October 2015 through November 2016. The applicant stated that these findings support their claim that Steripath® ISDD® reduces the risk of blood culture contamination.

The applicant submitted the Bauman, K, poster,[580] where investigators seeking to lower the blood culture contamination rate at the Inova Fairfax Medical Center found that Steripath® Gen2 implementation reduced their blood culture contamination rate by 81.5% when compared to conventional methods of sample acquisition. The trial use of Steripath® Gen2 lasted for one year, and results were compared to conventional methods for the year preceding the trial. According to the applicant, findings support the claim that Steripath® reduces the risk of blood culture contamination, while historical patient data from this hospital supported the claim that the lower contamination rate Steripath® enables will translate into a reduced patient length of stay of one day per avoided false positive event.

The applicant submitted the Blakeney J, et al.[581] poster, a prospective controlled study comparing the use of Steripath® ISDD® to standard collection methods and the effect on blood culture contamination rates. Over a 16-week period, participants' blood was collected using both the Steripath® and conventional methods, with each being recorded. Per the applicant, outcomes showed that Steripath® ISDD® implementation reduced Beebe Healthcare's blood culture contamination rate by 74.6 percent when compared to conventional methods of sample acquisition. The applicant stated that the findings support the claim that Steripath® ISDD® reduces the risk of blood culture contamination.

[578] Zimmerman, F. et al. ''Reducing blood culture contamination using an initial specimen diversion device.''*American Journal of Infection Control* 47.7 (2019): 822–826.

[579] Bell M, et al. Effectiveness of a novel specimen collection system in reducing blood culture contamination rates. Journal of Emergency Nursing 44.6 (2018): 570–575.

[580] Bauman, K. ''Don't Stick Me Again! Reducing Blood Culture Contamination'' Poster presented at: Emergency Nursing Annual Conference.

[581] Blakeney J, et al. ''Reduction of Blood Culture Contamination Using Initial Specimen Diversion Device''Poster presented at: American Society for Microbiology Annual Meeting (2018).

The applicant submitted the Church K, et al.[582] prospective controlled study, which showed that investigators at the Medical University of South Carolina emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 73.6 percent when compared to conventional methods of sample acquisition. In this 20-month study, nurses were given autonomy to decide if a patient would be best served by the Steripath® Gen2 device or conventional methods, with choices being recorded. The uptake rate of the Steripath® Gen2 device was 66%, with exclusions being uncooperative patients and difficult to stick patients.

The applicant submitted the Gauld L, et al.[583] study, an eight month long prospective controlled study which showed that investigators seeking to lower the blood culture contamination rate at the Medical University of South Carolina emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 86.3 percent when compared to conventional methods of sample acquisition.

The applicant submitted a poster, Lanteri C, et al.,[584] with preliminary data and a paper, Huss, J, et al.,[585] that includes all of the poster data with additional data gathered. This prospective controlled study at Brooke Army Medical Center showed that Steripath® Gen2 ISDD® implementation reduced blood culture contamination rate by 91.7 percent from September 2015 through January 2016, and 89.7 percent from September 2015 through March 2016 when compared to conventional methods of sample acquisition.

The applicant submitted the Rupp M, et al.[586] paper, which is a 12-month, single center, prospective, controlled, open label trial. Investigators at the University of Nebraska Medical Center emergency department seeking to gauge the efficacy of the Steripath® Gen2 ISDD® without confounding variables conducted a matched-set controlled study and found that Steripath® implementation reduced their blood culture contamination rate by 87.6 percent when compared to conventional methods of sample acquisition.

The applicant submitted the Stonecypher K, et al.[587] 8 week pilot study, which showed that investigators at the Michael E. DeBakey VA Medical Center emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 83.1 percent when compared to conventional methods of sample acquisition.

The applicant submitted the Tompkins L, et al.[588] abstract, which showed that investigators seeking to lower the blood culture contamination rate at Stanford Health Care found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 100 percent over a 4-month period when compared to conventional methods of sample acquisition. According to the applicant, full results are anticipated but not presently published.

The applicant submitted the Tongma C, et al.[589] prospective controlled study, which showed that investigators seeking to lower the blood culture contamination rate at Rush University Medical Center emergency department found that Steripath® Gen2 ISDD® implementation reduced their blood culture contamination rate by 87.0 percent when compared to conventional methods of sample acquisition. The 6-month study was split into an initial 3 months of usual care and a subsequent 3 months using the Steripath® Gen2 ISDD®.

The applicant provided the following studies to support secondary claims of substantial clinical improvement:

The applicant submitted the Buchta C, et al.[590] animal (pig) model study, in which investigators hypothesized that despite proper skin antiseptic use, contamination may occur because flora from deeper regions (such as pores) are not effectively eliminated. The applicant stated that results confirmed the hypothesis that cannula may cause tissue fragments to be punched in the process of blood sample acquisition, supporting the mechanism by which Steripath® Gen2 ISDD® primarily addresses blood culture contamination (that is, diversion).

The applicant submitted the Rhee C, et al.[591] retrospective cohort study, which featured adult patients admitted to 409 academic, community, and Federal hospitals from 2009–2014. Investigators sought to estimate national sepsis incidence and trends, concluding that sepsis was present in 6 percent of adult hospitalizations and 35 percent of hospitalizations resulting in death. According to the applicant, this helps put into context the role of Steripath® ISDD® in improving the efficacy of the primary tool used to guide therapy for bloodstream infections: blood culture.

The applicant submitted the Zimmerman F, et al.[592] paper (a randomized clinical trial) and the Binkhamis K and Forward K[593] paper (a prospective controlled study), which demonstrated that manual diversion reduced blood culture contamination rate by 60.0 percent and 28.2 percent, respectively, when compared to conventional methods of sample acquisition.

The applicant also submitted the Patton R and Schmitt T[594] prospective controlled study, which showed that investigators seeking to trial manual diversion of 1 mL to lower the blood culture contamination rate at the Northwest Hospital and Medical Center Emergency Department found that manual diversion reduced their blood culture contamination rate by 43.8 percent when compared to conventional methods of sample acquisition. The applicant further stated that the findings additionally support the volume of diversion utilized by Steripath® Micro™ ISDD®.

[582] Church K, et al. ''Novel Blood Culture Collection Device Reduces False-Positive Blood Cultures, Saves Costs, and Increases Accuracy of Bloodstream Infection Diagnosis'' Poster presented at: IHI National Forum (2017).

[583] Gauld L, et al. ''Reducing the laboratory cost of false-positive blood cultures in the adult emergency department.'' Poster presented at: IHI National Forum on Quality Improvement in Healthcare (2016).

[584] Lanteri C, et al. ''Reduction of Blood Culture Contaminations in the Emergency Department.'' Poster presented at: Department of Defense Healthcare Quality and Safety Awards (2016).

[585] Huss, Jody L, et al. ''Reducing Blood Culture Contamination with the Steripath® Blood Collection Kit.'' Uniformed Services University, 2016

[586] Rupp M, et al. ''Reduction in blood culture contamination through use of initial specimen diversion device.'' Clinical Infectious Diseases 65.2 (2017): 201–205.

[587] Stonecypher K, et al. ''ER Pilot Leads to Hospital-wide Implementation of Blood Culture Device'' Poster presented at: Emergency Nurses Association Annual Conference (2018)

[588] Tompkins L, et al. ''Eliminating Blood Culture Contamination with an Initial-Specimen Diversion Device'' Abstract presented at: IDWeek (2020).

[589] Tongma C, et al. ''Significant Reduction of Blood Culture Contamination in the Emergency Department (ED) Using the Steripath® Blood Diversion Device.'' Poster presented: Infectious Diseases Society of America IDWeek Conference, Fall (2017).

[590] Buchta C, et al. Skin plugs in phlebotomy puncture for blood donation. *Wiener klinische Wochenschrift* 117.4 (2005): 141–144.

[591] Rhee C, et al. Incidence and trends of sepsis in US hospitals using clinical vs claims data, 2009–2014. *JAMA* 318.13 (2017): 1241–1249.

[592] Zimmerman F, et al. Modification of blood test draw order to reduce blood culture contamination: a randomized clinical trial. *Clinical Infectious Diseases* 71.5 (2020): 1215–1220.

[593] Binkhamis K and Forward K. Effect of the initial specimen diversion technique on blood culture contamination rates. *Journal of Clinical Microbiology* 52.3 (2014): 980–981.

[594] Patton R and Schmitt T. Innovation for reducing blood culture contamination: initial specimen diversion technique. *Journal of Clinical Microbiology* 48.12 (2010): 4501–4503.

The applicant also submitted the Syed S, et al.[595] preintervention and postintervention study, which showed that investigators at the AMITA Health Saint Francis Hospital Emergency Department found that manual diversion reduced their blood culture contamination rate by 30.9 percent when compared to conventional methods of sample acquisition.

According to the applicant, the findings from these four studies support the claim that manual diversion reduces the risk of blood culture contamination relative to conventional methods of sample acquisition. We note that these studies discussed manual diversion and not Steripath® Micro™ or other diversion devices.

The applicant submitted the Alahmadi Y, et al.[596] study, which is a retrospective case-control study that showed that false positive blood cultures were associated with an average 5.4 day increase in patient length of stay and average increases of more than $7,500 in total charges to a healthcare system. The applicant also submitted the Bates D, et al.,[597] which is a prospective controlled study that showed false positive blood cultures were associated with an average of a 4.5 day increase in patient length of stay and average increases of more than $4,000 in total charges to a healthcare system. According to the applicant, investigators also noted that contaminants were independently correlated with a 39 percent increase in antibiotic charges.

The applicant provided a study to support its claim that the Steripath® ISDD® reduces the average length of stay for patients requiring blood culture, thereby lowering their risk of hospital-acquired infections (HAI) and conditions (HAC). The applicant explained that the Skoglund E, et al.[598] decision tree health care economic model paper showed that investigators found that overall, each false positive blood culture was on average associated with 2 day increases in patient length of stay and an average increase of more than $4,500 in total charges to a healthcare system. According to the applicant, Steripath® ISDD® implementation may reduce costs associated with contamination and reduce the average patient length of stay.

The applicant provided four studies to support its claim that Steripath® ISDD® reduces the inappropriate administration of vancomycin and other antibiotics to drive antibiotic stewardship. The applicant submitted the Chang D, et al.[599] poster, a retrospective, nonrandomized study that recorded the San Antonio Military Medical Center Emergency Department's days of therapy (DOT) of vancomycin for 18 months as a baseline. Then, the hospital implemented a new blood culture test, and recorded the DOT of vancomycin for 7 months. Subsequently, the hospital implemented the Steripath® Gen2 device and recorded the DOT of vancomycin for an additional 14 months to complete the 39-month trial. Investigators found that Steripath® Gen2 ISDD® implementation reduced vancomycin days of therapy by 14.4 days per 1,000 patient days when compared to conventional methods of sample acquisition. According to the applicant, findings from the study, as reported by the study authors, support the claim that Steripath® ISDD® reduces the unnecessary administration of antibiotics by reducing the rate of false positive blood cultures.

The applicant also submitted the Souvenir D, et al.[600] cohort study of 3,276 cultures of blood from 1,433 patients in which investigators found that physicians treated almost half of all patients receiving a false positive blood culture result with antibiotics, with vancomycin misuse occurring in 34 percent of patients. The applicant also submitted the Heijden Y, et al.[601] study in which investigators found that physicians treated 27% of patients receiving a false positive blood culture result with antibiotics unnecessarily, with the median antibiotic regimen being 7 days in length. The applicant also submitted the Bates study,[602] as discussed previously, which showed contaminants were independently correlated with a 39 percent increase in antibiotic charges.

According to the applicant, as Steripath® ISDD® is designed to reduce the incidence of blood culture contamination, Steripath® ISDD® implementation may reduce unnecessary antibiotic administration while supporting antimicrobial stewardship.

We have the following concerns regarding the substantial clinical improvement criterion. We note that much of the evidence submitted by the applicant to support that Steripath® Micro™ represents a substantial clinical improvement over existing technologies speaks to the overall clinical value of reducing blood contamination, or the benefit of manual diversion over no diversion, but does not directly link the Steripath® Micro™ to improved clinical endpoints. We note that the applicant stated that all of the studies provided that address the specific technology used to reduce blood contamination through diversion of the initial sample during blood collection utilized the Steripath® Gen2 ISDD®, not the Steripath® Micro™ ISDD® and we therefore question whether we have sufficient information to assess the clinical impact of Steripath® Micro™. Furthermore, the applicant did not present any clinical data to compare Steripath® Micro™ ISDD® to the Steripath® Gen2 ISDD®. We also note that comparative studies between Steripath® Micro™ and either manual diversion or competitor devices were not provided, and we question whether the standard of care used in the studies (that is, no diversion) is an appropriate comparator against which to test this technology. Additionally, we note that the applicant did not provide any clinical data demonstrating that the Steripath® Micro™ directly reduced length of stay, *C. difficile* infections, or other secondary results of antibiotic overuse. We are interested in any clinical data that directly links the Steripath® Micro™ to these outcomes.

Finally, we note that the claim of gentle negative pressure in support of the applicant's assertion that the technology would provide a treatment option for a new patient population was not addressed by any of the studies submitted. In addition, no data was supplied that quantified appropriate levels of negative pressure for either the

[595] Syed S, et al. Diversion Principle Reduces Skin Flora Contamination Rates in a Community Hospital. *Archives of Pathology & Laboratory Medicine* 144.2 (2020): 215–220.

[596] Alahmadi Y, et al. Clinical and economic impact of contaminated blood cultures within the hospital setting. *Journal of Hospital Infection* 77.3 (2011): 233–236.

[597] Bates D, et al. Contaminant blood cultures and resource utilization: the true consequences of false-positive results. *JAMA* 265.3 (1991): 365–369.

[598] Skoglund E, et al. Estimated clinical and economic impact through use of a novel blood collection device to reduce blood culture contamination in the emergency department: a cost-benefit analysis.

Journal of Clinical Microbiology 57.1 (2019).

[599] Chang D, et al. ''Impact of blood culture diversion device on molecular pathogen identification on vancomycin use.'' Poster presented at: Society for Healthcare Epidemiology of America (2017).

[600] Souvenir D, et al. Blood cultures positive for coagulase-negative staphylococci: antisepsis, pseudobacteremia, and therapy of patients. *Journal of Clinical Microbiology* 36.7 (1998): 1923–1926.

[601] Heijden, Yuri F., et al. ''Clinical impact of blood cultures contaminated with coagulase-negative staphylococci at an academic medical center.'' Infection Control and Hospital Epidemiology 32.6 (2011): 623.

[602] Bates D, et al. Contaminant blood cultures and resource utilization: the true consequences of false-positive results. *JAMA* 265.3 (1991): 365–369

typical or DIVA populations. Furthermore, no data was provided which compared the asserted appropriate level of negative pressure to levels of negative pressure created by the Steripath® Micro™ and Steripath® Gen2 devices. We are interested in any evidence of clinical improvement using the Steripath® Micro™ ISDD® in the specific population identified by the applicant, the difficult intravenous access population.

We are inviting public comments on whether the Steripath® Micro™ ISDD® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Steripath® Micro™ ISDD®.

q. StrataGraft™ Skin Tissue

Stratatech Corporation, a Mallinckrodt company, submitted an application for new technology add-on payments for the StrataGraft™ skin tissue (''StrataGraft'') for topical application for FY 2022. The applicant describes StrataGraft™ skin tissue as a viable, bioengineered, regenerative skin construct (BRSC) consisting of an epidermal layer of viable, fully stratified, allogeneic human NIKS® [603] keratinocytes growing on a dermal layer composed of viable human dermal fibroblasts embedded in a collagen-rich matrix. The applicant noted that StrataGraft™ is intended for the treatment of adult patients with severe thermal burns that contain intact dermal elements and require surgical intervention (hereinafter referred to as severe thermal burns [STB]). The applicant stated that StrataGraft™ skin tissue is produced in a rectangular format of approximately 100 cm^2, approximately 8 cm by 12.5 cm.

The applicant explained that the StrataGraft™ skin tissue promotes durable wound closure and regenerative healing for adult patients with STB. The applicant stated that in addition to providing immediate wound coverage and epidermal barrier function, the viable and metabolically active keratinocytes and fibroblasts in StrataGraft™ skin tissue provide sustained expression and secretion of growth factors, cytokines, and wound healing factors, which are anticipated to promote regenerative healing. The applicant stated that the StrataGraft™ skin tissue does not engraft; rather, it promotes regenerative healing and is replaced by the patient's own cells, eliminating the need for autografting to attain definitive closure of treated wounds.

The applicant explained that a thermal burn is the most common type of burn injury and accounts for approximately 86 percent of burn cases.[604] The applicant noted that burns are classified according to the depth of tissue injury as superficial (first-degree burns), partial-thickness (superficial and deep partial-thickness; second-degree burns), full-thickness (FT, third-degree burns), and fourth-degree burns (burns that have injured deeper structures such as muscle, fascia, and bone).[605] [606] The applicant also noted the percentage of total body surface area (TBSA) determines burn severity and directly correlates with mortality.[607]

The applicant stated that in the U.S., approximately 500,000 burn injuries receive emergency medical treatment each year, leading to 40,000 burn injury hospitalizations with 30,000 at hospital burn centers.[608] [609] The applicant noted that children and the elderly represent especially vulnerable populations at increased risk for death due to the skin loss and its complications.[610] The applicant explained that in 2013, the rate of burn-related hospital stays was highest for infants aged younger than 1 year (29.6 per 100,000 population) and older adults (20.7 per 100,000 population for adults aged 65–84 and 26.3 per 100,000 population for adults aged 85 and older).[611] The applicant also stated that unintentional fire or burn injuries was the 8th leading cause of death in those 65 years or older.[612]

The applicant explained that today, 96.7 percent of burn patients treated in burn centers will survive. The applicant noted that many of those survivors will sustain serious scarring and life-long physical disabilities.[613] The applicant stated that burn injuries pose a significant burden to patients; they can have a considerably negative effect on the patient's health-related quality of life (HRQoL), which was estimated to be reduced by 30 percent at the time of injury and by 9 percent in the long term.[614] The applicant explained that although most functional domains affected by burn injuries recover over time, HRQoL scores pertaining to physical and emotional role participation, anxiety, depression, pain, work, and heat sensitivity remained low at 12 months after the injury.[615]

The applicant explained that the standard of care for STB injuries is early excision and skin grafting.[616] [617] [618] The applicant noted that common surgical interventions for burn injury include: escharotomy, debridement, excision, and skin grafting.[619] The applicant explained that these burns have been treated with autografts, allografts, and xenografts in the past. The applicant stated that autologous grafts (autografts) are used most frequently because of the

[603] Registered trademark of Stratatech Corporation, Madison, WI

[604] Schaefer TJ, Tannan SC. Thermal Burns. [Updated 2020 Jun 7]. In: StatPearls [internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. *https://www.ncbi.nlm.nih.gov/books/NBK430773//.*

[605] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: an expert panel white paper. J Burn Care Res. 2013;34(2):e60-e79.

[606] Rice PL, Orgill DP. Assessment and classification of burn injury. UpToDate. *https://www.uptodate.com/contents/assessment-and-classification-of-burn-injury.* Literature review current through September 2020. Accessed September 25, 2020.

[607] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[608] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020

[609] HCUPnet, Healthcare Cost and Utilization Project. Agency for Healthcare Research and Quality, Rockville, MD. *https://hcupnet.ahrq.gov/.* Accessed June 5, 2019.

[610] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020.

[611] McDermott KW, Weiss AJ, Elixhauser A. Burn-Related Hospital Inpatient Stays and Emergency Department Visits, 2013: Statistical Brief #217. 2016 Dec. In: Healthcare Cost and Utilization Project (HCUP) Statistical Briefs [internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2006 Feb. *https://www.ncbi.nlm.nih.gov/books/NBK409513/.* Accessed September 30, 2020.

[612] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020

[613] Burn Injury Fact Sheet. American Burn Association. *https://ameriburn.org/wp-content/uploads/2017/12/nbawfactsheet_121417-1.pdf.* Published February 2018. Accessed July 1, 2020.

[614] Miller T, Bhattacharya S, Zamula W, et al. Quality-of-life loss of people admitted to burn centers, United States. Qual Life Res. 2013;22(9):2293–2305.

[615] Spronk I, Legemate C, Oen I, van Loey N, Polinder S, van Baar M. Health related quality of life in adults after burn injuries: A systematic review. PLoS One. 2018;13(5):e0197507. Published 2018 May 24.

[616] Bittner EA, Shank E, Woodson L, Martyn JA. Acute and perioperative care of the burn-injured patient. Anesthesiology. 2015;122(2):448–464.

[617] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[618] Ibid.

[619] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: an expert panel white paper. J Burn Care Res. 2013;34(2):e60-e79.

problems of infection and rejection when using allografts or xenografts.[620]

The applicant explained that autografting involves surgical harvesting of healthy tissue from the patient (donor site) and transplantation of this skin to an injured site on the same patient.[621] The applicant noted that autografts can be harvested as split thickness or full thickness. According to the applicant, split-thickness skin grafts (STSGs), also called partial-thickness grafts, transfer a portion of the donor site skin, including the epidermis and some of the underlying dermis. The applicant also explained that this allows the donor site to heal from the epidermal elements left behind. The applicant also stated that full-thickness skin grafts (FTSGs) harvest the entire layer of skin as the graft; no dermal or epidermal elements remain at the donor site, which must be closed by local advancement of the adjoining skin or by a secondary local flap. The applicant stated that the process of revascularization takes longer for an FTSG than for an STSG because of the increased thickness of the tissue.[622]

The applicant explained that early excision and skin grafting reduce the chance of wound infections and systemic sepsis, and have become the standard of care.[623] [624] [625] The applicant noted that without autografting, an STB that contains some dermal elements usually requires greater than 3 weeks to heal, thereby increasing the risk for infection and other complications that may lead to the development of significant scarring and contracture.[626] [627] [628] The applicant stated that while STBs require surgical debridement and grafting, superficial first-degree burns do not;[629] however, in the acute phase of the burn injury, the clinical presentation of the severely injured burn patient usually involves a range of burn depths from a superficial burn to a FT burn.[630]

The applicant explained that although autografting is effective in closing wounds and has been a standard treatment for decades, it has limitations. The applicant stated that donor sites are often associated with several complications, including excessive pain, pruritus, infection, dyschromia, hypertrophic scarring, delayed healing, and the potential for conversion to a FT wound.[631] The applicant also noted that donor-site pain is typically more painful than that in the treatment (burned) site and may become chronic.[632] [633] In patients with burns of 50–60 percent TBSA, autograft is limited by donor-site availability.[634] The applicant explained that donor sites may be re-harvested if they heal in time without infection; however, this practice can lead to prolonged hospitalization and decreased quality of the skin from re-harvested sites. The applicant stated that after patients undergo skin grafting, in the long term, both the grafted wound site and the donor site require continuous physical and rehabilitative therapy to maintain the range of movement, minimize scar and contracture development, and maximize functional ability.[635]

The applicant noted that autografting is especially undesirable in vulnerable patient populations, such as the elderly. The applicant stated that the healing of donor sites may be delayed or even lacking in elderly patients or patients whose wound-healing capabilities are compromised.[636] The applicant explained that because patients in these populations have thinner dermis and epidermis than non-elderly adults,[637] [638] there is a higher likelihood that the donor sites will go deep into the dermis during harvest or transform into FT wounds with their anatomical characteristics. The applicant stated that these patients are disproportionately affected and are at increased risk for death due to the skin loss and its complications.[639] The applicant also noted that the American College of Surgeons (ACS) developed guidelines to educate surgeons and other medical professionals about the significance of older adult burns and evidence-based prevention activities.[640]

The applicant stated that burn injuries result in substantial economic burden for healthcare systems and society. The applicant noted the average total hospital charges for a surviving patient with burns was estimated to be $98,062 and a patient who did not survive burns was estimated at $309,546.[641] For patients undergoing inpatient autografting, the applicant asserted that significant healthcare costs were observed during the first year, including per patient mean all-cause healthcare costs which ranged from $155,272 to $184,805.[642] The applicant explained that the primary cost driver in the first year was the cost incurred from the initial inpatient episode with autografting, accounting for 85 percent of the total costs.[643]

The applicant stated that there is currently no skin replacement product approved or available that leads to durable wound closure while

[620] Shevchenko RV, James SL, James SE. A review of tissue-engineered skin bioconstructs available for skin reconstruction. J R Soc Interface. 2010;7(43):229–258.

[621] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[622] Leon-Villapalos J. Skin autografting. UpToDate. *https://www.uptodate.com/contents/skin-autografting*. Literature review current through September 2020. Accessed October 1, 2020.

[623] Bittner EA, Shank E, Woodson L, Martyn JA. Acute and perioperative care of the burn-injured patient. Anesthesiology. 2015;122(2):448–464.

[624] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82

[625] Id.

[626] Deitch EA, Wheelahan TM, Rose MP, Clothier J, Cotter J. Hypertrophic burn scars: analysis of variables. J Trauma. 1983;23(10):895–898.

[627] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: an expert panel white paper. J Burn Care Res. 2013; 34(2):e60–79.

[628] Shupp JW, Nasabzadeh TJ, Rosenthal DS, Jordan MH, Fidler P, Jeng JC. A review of the local pathophysiologic bases of burn wound progression. J. Burn Care Res. 2010; 31(6):849–873.

[629] Bittner EA, Shank E, Woodson L, Martyn JA. Acute and perioperative care of the burn-injured patient. Anesthesiology. 2015;122(2):448–464.

[630] Ibid.

[631] 4 Osborne SN, Schmidt MA, Harper JR. An Automated and Minimally Invasive Tool for Generating Autologous Viable Epidermal Micrografts. Adv Skin Wound Care. 2016;29(2):57–64.

[632] Birchall MA, Varma S, Milward TM. The Moriarty sign: an appraisal. Br J Plast Surg. 1991;44(2):149–150.

[633] Sinha S, Schreiner AJ, Biernaskie J, et al. Treating pain on skin graft donor sites. J. Trauma Acute Care Surg. 2017;83(5)954–964.

[634] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

[635] Procter F. Rehabilitation of the burn patient. Indian J Plast Surg. 2010;43(Suppl):S101–S113.

[636] Bradow BP, Hallock GG, Wilcock SP. Immediate Regrafting of the Split Thickness Skin Graft Donor Site Assists Healing. Plast Reconstr Surg Glob Open. 2017;5(5):e1339. Published 2017 May 23.

[637] King A, Balaji S, Keswani SG. Biology and function of fetal and pediatric skin. Facial Plast Surg Clin North Am. 2013;21(1):1–6.

[638] Wainwright DJ, Bury SB. Acellular dermal matrix in the management of the burn patient. Aesthet Surg J. 2011;31(7 Suppl):13S–23S.

[639] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114

[640] Statement on Older Adult Burn Prevention. American College of Surgeons (ACS). *https://www.facs.org/aboutacs/statements/81-older-adult-burn*. Published January 1, 2018. Accessed September 26, 2020.

[641] American Burn Association. National Burn Repository 2019 update. 2019.

[642] Yu TC, Zhang X, Smiell J, Zhou H, Tan R, Boing E, Tan H. Healthcare resource utilization, treatment patterns, and cost of care among patients with thermal burns and inpatient autografting in two large privately insured populations in the United States. Burns. 2020;46(4):825–835.

[643] Ibid.

eliminating the need for harvesting an autograft.[644] [645]

The applicant explained that skin substitutes are a heterogeneous group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds. The applicant stated that the aim of skin substitutes is to replicate the properties of the normal skin,[646] and to provide the protective barrier function until definitive closure of the skin.[647] The applicant noted that synthetic skin substitutes need to be removed or undergo biodegradation or resorption so the skin can heal and regenerate.[648] The applicant also stated that biological skin substitutes have an architecture that resembles native skin and may allow the construction of a more natural new dermis.[649]

The applicant explained that skin substitutes are an important adjunct in the management of acute or chronic wounds and can be used to cover defects following burns or other injuries, or for reconstruction, such as for release of extensive severe post-burn contractures.[650] [651] The applicant also stated that Kumar's 3-category system, as shown in the table that follows, is currently the most frequently used classification system in the field. However, the applicant notes that there is no universally accepted classification system that allows for simple categorization of all the products that are commercially available.[652] The applicant stated that several biologic and biosynthetic materials are currently used as skin substitutes to temporarily cover wounds. The applicant provided the following table which, according to the applicant, classifies skin substitutes according to Kumar (2008) and summarizes the applicant's assertions regarding existing skin substitute products.

Skin substitute classification according to Kumar (2008)[653]

Class	Description	Sub-Category	Subdivision	Product Example
I	Temporary, impervious dressing material with mecahnical traits of the epidermis; lack keratinocytes	Single Layered Materials	Naturally occurring membrane or cover as biological dressing substitute	Biomembrane® Biocompatible vegetal membranes derived from the Hevea brasiliensis rubber tree
			Single-layer synthetic skin dressing material substitute	Tegaderm™, Opsite™, Dermafilm™, Nexfill®
		Bi-layered tissue-engineered materials		TransCyte®
II	Single-layer skin substitutes (epidermal or dermal)	Epidermal substitutes - similar to human epidermis; prone to breakdown; poor healing outcomes		Epice®, EpiDex®, Laserskin®, MySkin™, BioSeed®, CellSpray™
		Dermal substitutes - composition that includes proteins found in the dermal matrix		Permacol®, Matriderm®, Alloderm®
III	Composite skin substitutes that replace both the dermal and epidermal layer	Skin graft (autografts, allografts, and xenografts)		Allograft from cadaver, xenograft from porcine origin
		Tissue-engineered skin		Apligraf® (cellular), Integra® (acellular), Biobrane®

The applicant stated that StrataGraft™ skin tissue is a novel BRSC which possesses many of the physical and biological properties of an ideal skin substitute, including both epidermis and dermis with a barrier function comparable to that of intact human skin.[654] The applicant asserted that upon FDA approval, StrataGraft™ skin tissue will be the only skin substitute for treatment of STB classified by the FDA as a biologic (as

[644] Kagan RJ, Peck MD, Ahrenholz DH, et al. Surgical management of the burn wound and use of skin substitutes: an expert panel white paper. J Burn Care Res. 2013;34(2):e60-e79.

[645] Carter JE, Holmes JH. The Surgical Management of Burn Wounds. 2016.

[646] Shahrokhi S. Skin substitutes. UpToDate. *https://www.uptodate.com/contents/skin-substitutes.* Literature review current through August 2020.

[647] MacNeil S. Progress and opportunities for tissue-engineered skin. Nature 2007;445(7130)874–880.

[648] Halim A, Khoo T, Shah JY. Biologic and synthetic skin substitutes: An overview. Indian J. Plast. Surg. 2010;43(3)23

[649] Ibid. Halim A, Khoo T, Shah JY. Biologic and synthetic skin substitutes: An overview. Indian J. Plast. Surg. 2010;43(3)23.

[650] Shahrokhi S. Skin substitutes. UpToDate. *https://www.uptodate.com/contents/skin-substitutes.* Literature review current through August 2020.

[651] Leon-Villapalos J. Skin autografting. UpToDate. *https://www.uptodate.com/contents/skin-autografting.* Literature review current through September 2020. Accessed October 1, 2020.

[652] Shahrokhi S. Skin substitutes. UpToDate. *https://www.uptodate.com/contents/skin-substitutes.* Literature review current through August 2020. Accessed September 25, 2020.

[653] Kumar P. Classification of skin substitutes. Burns. 2008;34(1):148–149.

[654] Schurr MJ, Foster KN, Centanni JM, et al. Phase I/II clinical evaluation of StrataGraft: a consistent, pathogen-free human skin substitute. J Trauma. 2009;66(3):866–874.

opposed to other available treatments that are medical devices) that promotes durable wound closure and regenerative healing, thereby reducing or eliminating the need of autologous skin harvesting. According to the applicant, on June 5, 2020, Mallinckrodt finalized the rolling submission of a Biologics License Application (BLA) to the FDA seeking approval to market StrataGraft™ skin tissue for the treatment of adult patients with STB. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving Stratagraft™. We note that the applicant submitted a request for approval for a unique ICD–10–PCS code for the use of Stratagraft™ beginning FY 2022.

The applicant explained that StrataGraft™ skin tissue is a viable BRSC that may be applied universally to patients, that is, it is not a patient-specific product. The applicant stated that the active cellular components of StrataGraft™ skin tissue are the viable and metabolically active allogeneic human NIKS® keratinocytes and normal human dermal fibroblasts (NHDF).

The applicant noted that StrataGraft™ skin tissue comprises an epidermal layer and a dermal layer. The applicant explained that the epidermal layer of StrataGraft™ skin tissue is composed of differentiated, multilayered, viable epidermal keratinocytes that are adherent through normal hemidesmosomes to a dermal equivalent.[655] The applicant stated that human epidermal keratinocytes used are NIKS® keratinocytes, a continuous and consistent source of well-characterized, non-tumorigenic, long-lived keratinocyte precursors that are derived from a single neonatal human foreskin donor. The applicant asserted that NIKS® keratinocytes have normal steady state of messenger ribonucleic acid (mRNA) and protein expression levels for autocrine regulators and growth factors such as transforming growth factor (TGF)-α, TGF-β1, epidermal growth factor, and c-myc, providing further evidence of the normal function of these cells.[656] The applicant also explained that NIKS® keratinocytes produce normal adhesion proteins (example, integrins and cadherins) that permit tight adherence to each other and the dermal equivalent.[657] The applicant stated that cell-cell and cell-substratum adhesions confer excellent handling characteristics to StrataGraft™ skin tissue, enabling it to be meshed and secured in place as is routinely done with STSGs. The applicant noted that the dermal layer of StrataGraft™ skin tissue contains NHDF derived from a single healthy tissue donor.

The applicant explained that viable cells within StrataGraft™ skin tissue express and secrete a wide variety of peptides, growth factors, and cytokines that are known to promote healing, thereby reducing or eliminating the need for autograft in the management of thermal burns.[658] The applicant also stated that no currently available technology (competitor) for the treatment of STB is characterized by the autologous (endogenous) tissue regeneration of the burned skin.

The applicant stated that the StrataGraft™ skin tissue is manufactured through organotypic culture under aseptic conditions in compliance with current Good Manufacturing Practices. The applicant explained that in organotypic culture, NIKS® keratinocytes undergo tissue-appropriate differentiation and stratification to produce a skin tissue that exhibits many of the structural and biological properties of intact human skin. The applicant noted that the epidermal layer of StrataGraft™ skin tissue exhibits typical production and organization of cell-type specific proteins (example, keratin, filaggrin, involucrin, and transglutaminase), development of a normal cornified envelope, and production of lipid-filled granules that are necessary for the generation and maintenance of robust epidermal barrier function similar to that found in vivo.[659]

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the mechanism of action of StrataGraft™ skin tissue in severe thermal burns is not the same or similar to an existing technology. The applicant states that StrataGraft™ skin tissue will be the first and only FDA-approved biologic for the treatment of STB that reduces or eliminates the need of autograft and for which the mechanism of action is a sustained expression and secretion of growth factors, cytokines, and wound healing factors, which are anticipated to promote regenerative healing and durable wound closure.[660] [661] The applicant explains that this unique mechanism of action is the reason StrataGraft™ skin tissue reduces or eliminates the need for harvest of donor site tissue.

With respect to the second criterion, whether a product would be assigned to the same MS–DRGs as existing technologies, the applicant indicated that the StrataGraft™ skin tissue would be assigned to the same MS–DRGs as cases representing patients who receive standard of care (autograft) or existing technologies used to treat STB. The applicant stated that the MS–DRGs in question do not differentiate between patients with burns of differential severity degree, in different body sites, due to thermal injury or corrosion, or with different percent TBSA involved.[662]

With respect to the third criterion, whether a product would be used to treat the same or similar type of disease and patient population, the applicant asserted that StrataGraft™ will treat the same or similar type of disease but not the same or similar patient population when compared to existing technologies. The applicant claimed that StrataGraft™ skin tissue will treat a burn patient population for whom the current standard of care and/or other available technologies may not be clinically feasible solutions to achieve durable wound closure. The applicant explains that in patients with burns of 50–60 percent of the TBSA, donor-site availability is limited.[663] The applicant also stated that autografting is especially

[655] Schurr MJ, Foster KN, Centanni JM, et al. Phase I/II clinical evaluation of StrataGraft skin tissue: a consistent, pathogen-free human skin substitute. J Trauma. 2009;66(3):866-874.

[656] Allen-Hoffmann BL, Schlosser SJ, Ivarie CA, Sattler CA, Meisner LF, O'Connor SL. Normal growth and differentiation in a spontaneously immortalized near-diploid human keratinocyte cell line, NIKS. J Invest Dermatol. 2000;114(3):444–455

[657] Ibid.

[658] Harvestine J, Pradhan-Bhatt S, Steiglitz BM, Maher RJ, Comer AR, Gratz KR, Allen-Hoffmann BL. StrataGraft® Skin Tissue, a Bioengineered Regenerative Skin Construct for Severe Acute Wounds. Poster presented at: 2020 Biomedical Engineering Society (BMES) Virtual Annual Meeting, October 14–17, 2020.

[659] Ibid.

[660] Proposed prescribing information. for Stratagraft™ skin tissue;. Submitted to FDA, April 2020.

[661] Harvestine J, Pradhan-Bhatt S, Steiglitz BM, Maher RJ, Comer AR, Gratz KR, Allen-Hoffmann BL. StrataGraft® Skin Tissue, a Bioengineered Regenerative Skin Construct for Severe Acute Wounds. Poster presented at: 2020 Biomedical Engineering Society (BMES) Virtual Annual Meeting, October 14–17, 2020.

[662] MDC 22 Burns. Non-Extensive Burns. In: ICD–10–CM/PCS MS–DRG v37.2 Definitions Manual. Centers for Medicare & Medicaid Services. *https://www.cms.gov/icd10m/version372-fullcode-cms/fullcode_cms/P0353.html.* Accessed October 1, 2020.

[663] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

undesirable in vulnerable patient populations, such as the elderly; healing of donor sites may be delayed or even lacking in elderly patients or patients whose wound-healing capabilities are compromised.[664] The applicant explained that these patients are disproportionately affected and are at increased risk for death due to the skin loss and its complications.[665] The applicant also states that the label for StrataGraft™ skin tissue will not be reserved for a patient population diagnosed with STB for whom standard-of-care treatment is not feasible or clinically desirable. The applicant asserts that this does not imply that StrataGraft™ skin tissue will not offer a treatment option to a new patient population.

With respect to the first criterion, we note that there may be other biologic dressings that use some combination of keratinocytes, collagen, glycosaminoglycans (GAGs), cytokines, chemokines, and/or other growth factors in either a single, double, or triple layer configuration. While StrataGraft™ may have a unique combination of these features, we are interested in further information on whether there are any dressings with a regenerative mechanism of action that may be approved for burns.

With respect to the third criterion, StrataGraft™ may treat the same or similar patient population as the standard of care or existing technologies to treat STB. While we agree that in patients with burns of 50–60 percent of the TBSA, donor-site availability is more limited, we observe that neither of the two pivotal studies included patients with burns of 50 percent or greater of the TBSA.[666] We are unclear whether this suggests Stratagraft™ is intended for treatment of patients with burns of less than 50 percent TBSA. We also question whether vulnerable patients, such as the elderly, are a new population as they are currently treated using standard of care or other technologies.

We are inviting public comments on whether Stratagraft™ is substantially similar to other technologies and whether Stratagraft™ meets the newness criterion.

With regard to the cost criterion, the applicant stated that Stratagraft™ skin tissue is seeking FDA approval for the proposed indication of treatment of adult patients with STBs that contain intact dermal elements and require surgical intervention. In order to identify the range of MS–DRGs that eligible patients may map to, the applicant conducted a claims search for cases that include ICD–10–CM codes for thermal burns of second, third degree, or those classified according to TSBA to identify cases eligible for use of Stratagraft™ skin tissue utilization. The applicant identified cases reporting ICD–10–CM codes for diagnoses of second-degree thermal burns, any location (T20.2XXX to T25.2XXX); third-degree thermal burns, any location (T20.3XXX to T25.3XXX); and thermal burns classified according to extent of body surface involved (T31.XX).

The applicant used the FY 2019 MedPAR Hospital LDS with the FY 2022 thresholds, and the FY 2019 IPPS/LTCH Final Rule Impact File and Standardizing File. The appliant's claim search in the aggregate identified 58,624 cases mapping to 21 MS–DRGs as listed in the following table. Of the total 21 MS–DRGs, only six had case volume greater than or equal to one percent across all cohorts and cumulatively represent 97.54 percent of cases. In cases where MS–DRGs had fewer than 11 discharges, the applicant imputed a minimum value of 11 cases for each MS–DRG.

[664] Bradow BP, Hallock GG, Wilcock SP. Immediate Regrafting of the Split Thickness Skin Graft Donor Site Assists Healing. Plast Reconstr Surg Glob Open. 2017;5(5):e1339. Published 2017 May 23.

[665] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[666] Girard D, Laverdet B, Buhé V, et al. Biotechnological Management of Skin Burn Injuries: Challenges and Perspectives in Wound Healing and Sensory Recovery. Tissue Eng Part B Rev. 2017;23(1):59–82.

Potential MS-DRGs Expected To Be Assigned To Stratagraft™ Skin Tissue-Eligible Inpatient Cases Listed In Descending Order According To Case Volume	
MS-DRG	**Description**
928	Full Thickness Burn w Skin Graft or Inhalation Injury w CC/MCC
929	Full Thickness Burn w Skin Graft or Inhalation Injury w/o CC/MCC
927	Extensive Burns or Full Thickness Burns w Mv >96 Hours w Skin Graft
935	Non-Extensive Burns
003	Ecmo or Tracheostomy w Mv >96 Hours or Pdx Except Face, Mouth And Neck w Major O.R. Procedure
940	O.R. Procedure w Diagnoses of Other Contact w Health Services w CC
904	Skin Grafts For Injuries w CC/MCC
941	O.R. Procedures w Diagnoses of Other Contact w Health Services w/o CC/MCC
939	O.R. Procedures w Diagnoses of Other Contact w Health Services w MCC
577	Skin Graft Except For Skin Ulcer or Cellulitis w CC
574	Skin Graft For Skin Ulcer or Cellulitis w CC
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC
901	Wound Debridements for Injuries w MCC
246	Percutaneous Cardiovascular Procedures w Drug-Eluting Stent w MCC Or 4+ Arteries or Stents
166	Other Respiratory System O.R. Procedures w MCC
906	Hand Procedures for Injuries
264	Other Circulatory System O.R. Procedures
573	Skin Graft for Skin Ulcer or Cellulitis w MCC
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders w CC
004	Tracheostomy w Mv >96 Hours or Pdx Except Face, Mouth and Neck w/o Major O.R. Procedure
854	Infectious and Parasitic Diseases w O.R. Procedure w CC

To demonstrate that the technology meets the cost criterion, the applicant first identified four separate patient cohorts: Cohort (1) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for reasons only related to thermal burns (n=14,774, MS–DRGs=21); Cohort (2) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for reasons only related to thermal burns, and who underwent excisional debridement in the inpatient setting (n= 13,640, MS–DRGs=20); Cohort (3) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for thermal burns, with or without other conditions (n=15,744, MS–DRGs=21); and Cohort (4) Patients with thermal burns of second or third degree in any body area, or thermal burns classified according to TBSA, who received autograft for thermal burns, with or without other conditions, and who underwent excisional debridement in the inpatient setting (n= 14,466, MS–DRGs=20). The applicant then identified eight analyses for the cost criterion: (1) Calculations for Cohort one (all MS–DRGs); (2) Calculations for cohort two (all MS–DRGs); (3) Calculations for Cohort three (all MS–DRGs); (4) Calculations for cohort four (all MS–DRGs); (5) Calculations for Cohort one (top 4 MS–DRGs by case volume); (6) Calculations for Cohort two (top 4 MS–DRGs by case volume); (7) Calculations for Cohort three (top 4 MS–DRGs by case volume); and (8) Calculations for Cohort 4 (top 4 MS–DRGs by case volume).

The applicant determined an average unstandardized case weighted charge per case of $173,650 for analysis one, $168,282 for analysis two, $178,530 for analysis three, $172,277 for analysis four, $158,851 for analysis five, $155,700 for analysis six, $162,377 for analysis seven, and $158,452 for analysis eight.

The applicant stated that charges for and related to the prior technologies were not removed from the cost analysis.

After calculating the average standardized charge per case for all scenarios, the applicant calculated the standardized charge per case for each MS–DRG. Next, the applicant applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges of 13.2 percent (1.13218). The applicant stated that the price for Stratagraft™ skin tissue has not yet been established and therefore it did not add charges for the technology. Lastly, the applicant calculated the final average inflated standardized charge per case and the inflated case weighted standardized charge per case for each scenario.

The applicant stated that, for analysis one, the final inflated average case-weighted standardized charge per case of $304,347 exceeded the average case-weighted threshold amount of $173,650 by $130,697. For analysis two, the final inflated average case-weighted standardized charge per case of $279,373 exceeded the average case-weighted threshold amount of $168,282 by $111,091. For analysis three, the final inflated average case-weighted standardized charge per case of $332,006 exceeded the average case-weighted threshold amount of $178,530 by $153,477. For analysis four, the final inflated average case-weighted standardized charge per case of $299,228 exceeded the average case-weighted threshold amount of $172,277 by $126,951. For analysis five, the final inflated average case-weighted standardized charge per case of $241,186 exceeded the average case-weighted threshold amount of $158,851 by $82,336. For analysis six, the final inflated average case-weighted standardized charge per case of $229,661 exceeded the average case-weighted threshold amount of $155,700 by $73,961. For analysis seven, the final inflated average case-weighted standardized charge per case of $257,800 exceeded the average case-weighted threshold amount of $162,377 by $95,423. For analysis eight, the final inflated average case-weighted standardized charge per case of $244,042 exceeded the average case-weighted threshold amount of $158,452 by $85,590.

The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, Stratagraft™ meets the cost criterion.

We invite public comment on whether Stratagraft™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that StrataGraft™ skin tissue is a substantial clinical improvement over existing technology for the treatment of adult patients with severe thermal burns with intact dermal elements because it achieves a significant rate of durable wound closure for patients with severe burns while minimizing or eliminating the complications associated with autograft harvest.

According to the applicant, the totality of the circumstances otherwise demonstrates that StrataGraft™ skin tissue, relative to technologies previously available, substantially improves the treatment of STB patients including Medicare beneficiaries. The applicant stated that because the benefits associated with its use are not accompanied by an increased incidence of adverse events as compared to autograft, StrataGraft™ skin tissue is a substantial clinical improvement.

The applicant explained that by significantly reducing or eliminating the harvest of donor sites, patients who receive StrataGraft™ skin tissue are spared short- and long-term sequelae and complications and, to a lesser extent, infection or conversion to a full-thickness wound of the donor sites.[667] The applicant stated that by significantly reducing or eliminating the need for autograft,[668] StrataGraft™ skin tissue is especially relevant for the elderly population where autograft is undesirable; these patients are disproportionately affected and are at increased risk for death due to the skin loss and its complications.[669] The applicant explained that aging and environmental factors can influence the severity of burns in vulnerable skin.[670] [671] The applicant stated that geriatric skin also exhibits slower wound healing and is at increased risk of excessive scarring.[672] [673] [674] [675] [676] According to the applicant, age-related changes in wound healing capacity can include delayed infiltration of immune cells, decreased secretion of growth factors, and altered collagen remodeling.[677]

The applicant further explained that use of StrataGraft™ skin tissue can preserve limited donor sites for the treatment of other wounds, such as areas of FT injury and wounds in cosmetically sensitive areas. The applicant noted that it may also reduce the need for repeated harvest of autograft donor sites, potentially reducing the number of surgical procedures and total length of time to wound closure. The applicant explained that burn injury is associated with a high prevalence of posttraumatic stress disorder, ranging between 11 percent and 50 percent across studies,[678] and may also lead to anxiety and depression due to scarring and body image concerns.[679] Lastly, the applicant stated that use of StrataGraft™ skin tissue reduces pain while offering a comparable scar quality to autograft.[680]

The applicant provided two controlled and randomized studies, STRATA2011 and STRATA2016, to support its claims of substantial clinical improvement. The applicant stated that with the exception of subject age (STRATA2011, 18 to 64 years of age; STRATA2016, ≥18 years of age), the inclusion and exclusion criteria for the two studies were similar. According to the applicant, the STRATA2016 study (NCT03005106—Phase 3 trial—71 patients) [681] [682] was a 12-month, open-

[667] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[668] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[669] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114

[670] Gosain A, DiPietro LA. Aging and wound healing. World J Surg. 2004;28(3):321–326.

[671] Landau M. Exogenous factors in skin aging. Curr Probl Dermatol. 2007;35:1–13.

[672] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[673] Gosain A, DiPietro LA. Aging and wound healing. World J Surg. 2004;28(3):321–326.

[674] Greenhalgh DG. Management of the skin and soft tissue in the geriatric surgical patient. Surg Clin North Am. 2015;95(1):103–114.

[675] Ibid.

[676] Gosain A, DiPietro LA. Aging and wound healing. World J Surg. 2004;28(3):321–326.

[677] Ibid.

[678] Summer GJ, Puntillo KA, Miaskowski C, et al. Burn Injury Pain: The Continuing Challenge. J. Pain 2007;8(7)533–548.

[679] Calotă DR, Nițescu C, Marinescu S, et al. Correlations between morphological appearance and psychosocial difficulties in patients with extensive burns who received allotransplant. Rom J Morphol Embryol. 2012;53(3 Suppl):703–711.

[680] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[681] StrataGraft skin tissue® Skin Tissue in the Promotion of Autologous Skin Regeneration of Complex Skin Defects Due to Thermal Burns That Contain Intact Dermal Elements. ClinicalTrials.gov. *https://clinicaltrials.gov/ct2/show/NCT03005106.* Accessed June 15, 2020.

[682] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy

Continued

label, multicenter, controlled, randomized study that evaluated the efficacy and safety of StrataGraft™ skin tissue in promoting autologous skin tissue regeneration of severe thermal burns. The applicant explained that the STRATA2011 study (NCT01437852—Phase 1b trial—30 patients)[683] [684] was a 12-month, open-label, multicenter, controlled, randomized, dose-escalation study that evaluated the safety, tolerability, and efficacy of StrataGraft™ skin tissue in promoting the healing of the STB component of complex skin defects due to thermal injury as an alternative to autografting. The applicant noted that, in both studies, eligible subjects had 3 percent to 49 percent TBSA burns with two comparable treatment sites that were prospectively identified, and the sites were randomized to receive either a single topical application of StrataGraft™ skin tissue or autograft, such that each subject received both treatments. The applicant noted that in this intrapatient comparator design, the area that was autografted served as a subject's own paired control.

To support the claim that the use of StrataGraft™ skin tissue significantly reduces the percent area of the treatment sites autografted, the applicant explained that the STRATA2016 study showed the average percent area of the StrataGraft™ skin tissue treatment site autografted by Month 3 was lower than the average percent area of the autograft control treatment site autografted by Month 3 (mean difference: 97.77 percent; $P < 0.0001$).[685] We note that the applicant did not provide detailed information regarding the measurement methodology.

To support the claim that StrataGraft™ skin tissue is effective in achieving durable wound closure similar to that of autografting, the applicant states that the STRATA2016 study showed that the majority of subjects (59 of 71 subjects, or 83.1 percent, with a 95 percent CI of 74.4 to 91.8) achieved durable wound closure of the StrataGraft™ skin tissue-treated site at Month 3 without the need for autograft harvest and placement.[686] The applicant also explained that the STRATA2011 study showed that no StrataGraft™ treatment sites required autografting by Day 28. The applicant noted that at Month 3 in the STRATA2016 study, 93.1 percent of StrataGraft™ treatment sites were assessed as closed. The applicant stated that all StrataGraft™ skin tissue-treated areas evaluated at 6 months and 12 months remained closed. The applicant noted that, when comparing these results to that of autografting, the proportion of wounds that achieved closure was not statistically different.[687]

To support the claim of reduction in donor site pain using StrataGraft, the applicant stated that the STRATA2016 study showed that the difference between the donor sites preserved for StrataGraft™ skin tissue treatment site failure and autograft donor sites in the average pain intensity through Day 14 based on the Wong-Baker FACES® Pain Rating Scale (FPRS)[688] was 2.40 ± 1.313 ($P < 0.0001$), indicating significantly less mean donor-site pain intensity in the reserved StrataGraft™ skin tissue donor sites compared with autograft donor sites.[689] The applicant also stated that the STRATA2011 study showed that patients experienced pain at harvested donor sites used for autograft, but minimal pain at unharvested donor sites that had been set aside for potential use with StrataGraft™ skin tissue.[690]

According to the applicant, the elimination of autografting leads to superior scar quality outcome of the presumptive StrataGraft™ skin tissue donor site (that is lack of scarring in the donor sites reserved for StrataGraft™ treatment site failure), which is a substantial clinical improvement. The applicant explained that the STRATA2016 study showed that the evaluation of scarring using the Patient and Observer Scar Assessment Scale (POSAS)[691] [692] observer total scores demonstrated a significant difference in scar quality between the StrataGraft™ skin tissue and autograft donor sites at Month 3, 10.0 ± 7.92 ($P < 0.0001$), favoring StrataGraft™ skin tissue.[693] The applicant stated that the STRATA2016 study showed scores for every POSAS category were lower for StrataGraft™ skin tissue donor sites when compared with autograft donor sites, indicating they were more like normal skin (that is, the patient's tissue in the donor sites reserved for StrataGraft™ failure were more like normal skin than tissue present in autograft donor sites that were harvested).[694] The applicant explained that the STRATA2011 study showed that observer POSAS total scores from the StrataGraft™ tissue treatment site and autograft were not significantly different throughout the study.[695] The applicant stated that the STRATA2011 showed that mean overall POSAS opinion scores of observers or patients decreased (that is, became more favorable) from Month 3 through Month 12 after application for both the StrataGraft™ tissue and autograft.[696]According to the applicant, although direct comparisons between StrataGraft™ skin tissue and other skin substitutes cannot be drawn, StrataGraft™ skin tissue, relative to device technologies previously available, improves the clinical outcomes of STB patients. The applicant stated that most skin substitutes do not claim to promote wound closure without the need for subsequent autograft because they have not been

and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[683] StrataGraft skin tissue® Skin Tissue as an Alternative to Autografting Deep Partial-Thickness Burns. ClinicalTrials.gov. *https://clinicaltrials.gov/ct2/show/NCT01437852*. Accessed June 15, 2020.

[684] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[685] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[686] Ibid.

[687] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[688] Wong-Baker FACES Foundation. *https://wongbakerfaces.org/*. Accessed July 1, 2020.

[689] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[690] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[691] Van de Kar AL, Corion LUM, Smeulders MJC, et al. Reliable and Feasible Evaluation of Linear Scars by the Patient and Observer Scar Assessment Scale. Plast. Reconstr. Surg. 2005;116(2)514–522.

[692] The Patient and Observer Scar Assessment Scale (POSAS). *https://www.posas.nl/*. Accessed July 1, 2020.

[693] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[694] Ibid.

[695] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[696] Ibid.

studied in this context,[697] while clinical studies for StrataGraft™ skin tissue assessed wound closure as a pre-specified endpoint.[698] [699] The applicant further stated that reparative healing mechanisms, used by most available skin substitutes, are more likely to result in scarring when compared with regenerative healing mechanisms used by StrataGraft.[700]

After reviewing the information provided by the applicant with regard to the substantial clinical improvement criterion, we note a lack of study data provided comparing StrataGraft™ to other biologic dressings and we are interested in further information related to whether there are any dressings that may be approved for burns that demonstrate durable wound closure. The applicant provided published results of one randomized trial (STRATA2011), but we question whether the sample size of 30 is adequately generalizable to the larger Medicare population. In addition, we note that the STRATA2016 study has not been published and the results of this study were not submitted in full, and we therefore may not have the complete outcomes and study results for these additional patients. We further note that in the studies provided, patients with 50 percent or greater TBSA burns were excluded. The applicant indicated that the product could be especially meaningful for patients with burns of 50–60 percent TBSA, but we question whether we can fully evaluate this claim because these patients were not assessed.

We are inviting public comments on whether StrataGraft™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for StrataGraft™ skin tissue.

r. Tecartus™ (brexucabtagene autoleucel)

Kite Pharma submitted an application for new technology add-on payment for FY 2022 for Tecartus™ (brexucabtagene autoleucel) (''Tecartus''). Tecartus is a CD19 directed genetically modified autologous T-cell immunotherapy for the treatment of adult patients with relapsed and refractory (r/r) mantle cell lymphoma (MCL). We note that Kite Pharma previously submitted an application for new technology add-on payments for Tecartus for FY 2021, as summarized in the FY 2021 IPPS/LTCH PPS proposed rule, under the name KTE–X19 (85 FR 32634).

Tecartus is a form of chimeric antigen receptor (CAR) T-cell immunotherapy that modifies the patient's own T-cells to target and eliminate tumor cells. More specifically, according to the applicant, Tecartus is a single infusion product consisting of autologous T-cells that have been engineered to express an anti-CD19 chimeric antigen receptor. According to the applicant, this therapy targets the CD19 antigen on the cell surface of normal and malignant B-cells. The applicant stated that Tecartus is different from other previously approved technologies because it has a distinct cellular product that requires a unique manufacturing process.

According to the applicant, MCL is a rare and aggressive subtype of non-Hodgkin lymphoma (NHL) with distinct characteristics[701] [702] that accounts for 3–10% of all cases of NHL in the United States and differs from diffuse large B-cell lymphoma (another subtype of NHL).[703] [704] [705]

The applicant stated that MCL has an annual incidence of 0.5 to 1 cases per 100,000 population with a male-to-female ratio of 3:1 with a median age at diagnosis for patients with MCL of 68 years.[706] MCL results from a malignant transformation of the B lymphocyle in the outer edge of a lymph node follicle (the mantle zone). Prognosis varies for r/r MCL, but the median survival for MCL is 3–5 years depending on the risk group (the Mantle Cell Lymphoma International Prognostic Index categorizes patients into low, intermediate and high risk groups), according to the applicant.[707] According to the applicant, the preferred first line therapy is bendamustine-rituximab which has decreased toxicity and improved progression-free survival as compared to rituximab with cyclophosphamide, doxorubicin, vincristine, and prednisone.[708] According to the applicant, rituximab is also the only approved therapy for maintenance for patients in remission. The applicant stated the median progression free survival ranges from 29–51 months with most of MCL patients eventually relapsing. The applicant contended that approximately 40% of patients end up with durable long-term remission after a chemoimmunotherapy first line therapy.[709] [710] [711]

The applicant indicated that there is no standard of care that exists for second-line and higher chemotherapy when a patient has relapsed or refractory MCL.[712] According to the applicant, second line therapies typically depend on the front line therapy utilized, comorbidities, the tumor's sensitivity to chemotherapy, and overall risk-benefit. According to the applicant, currently available options for second line therapy include:

[697] Stone Ii R, Natesan S, Kowalczewski CJ, et al. Advancements in Regenerative Strategies Through the Continuum of Burn Care. Front Pharmacol. 2018;9:672. Published 2018 Jul 9.

[698] Holmes JH, Schurr MJ, King BT, et al. An open-label, prospective, randomized, controlled, multicenter, phase 1b study of StrataGraft skin tissue versus autografting in patients with deep partial-thickness thermal burns. Burns 2019;45(8)1749–1758.

[699] Holmes JH, Shupp JW, Smith DJ, et al. T5: Preliminary analysis of a phase 3 open-label, controlled, randomized trial evaluating the efficacy and safety of a bioengineered regenerative skin construct in patients with deep partialthickness thermal burns. J. Burn Care Res. 2020;41(Supplement_1)S3–S4.

[700] Hu MS, Maan ZN, Wu JC, et al. Tissue engineering and regenerative repair in wound healing. Ann Biomed Eng. 2014;42(7):1494–1507.

[701] Fakhri B, Kahl B. Current and emerging treatment options for mantle cell lymphoma. Ther Adv Hematol. 2017;8(8):223–34.

[702] National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology; B-cell Lymphomas, Version 1.2019 [November 30, 2018]. 2017 Available from: *https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf*.

[703] The Non-Hodgkin's Lymphoma Classification Project. A clinical evaluation of the International Lymphoma Study Group classification of non-Hodgkin's lymphoma. Blood. 1997;89(11):3909–3918.

[704] Zhou Y, et al. Incidence trends of mantle cell lymphoma in the United States between 1992 and 2004. Cancer. 2008;113(4):791–798.

[705] Teras LR, et al. 2016 US lymphoid malignancy statistics by World Health Organization subtypes CA Cancer J Clin. 2016;6:443–459.

[706] Fu S, et al. Trends and variations in mantle cell lymphoma incidence from 1995 to 2013: A comparative study between Texas and National SEER areas. Oncotarget. 2017;8(68):112516–29.

[707] Cheah CY, et al. Mantle cell lymphoma. *J Clin Oncol.* 2016;34:1256–1269.

[708] Rummel MJ, et al. Bendamustine plus rituximab versus CHOP plus rituximab as first-line treatment for patients with indolent and mantle-cell lymphomas: an open-label, multicentre, randomized, phase 3 non-inferiority trial. Lancet. 2013;381: 1203–1210.

[709] Flinn IW, et al. First-line treatment of patients with indolent non-Hodgkin lymphoma or mantle-cell lymphoma with bendamustine plus rituximab versus R–CHOP or R–CVP: results of the BRIGHT 5-year follow-up study. *J Clin Oncol.* 2019 Apr 20;37(12):984–991. doi: 10.1200/JCO.18.00605. Epub 2019 Feb 27.

[710] LaCasce AS, et al. Comparative outcome of initial therapy for younger patients with mantle cell lymphoma: an analysis from the NCCN NHL Database. *Blood.* 2012;19(9):2093–2099.

[711] Lenz G, et al. Immunochemotherapy with rituximab and cyclophosphamide, doxorubicin, vincristine, and prednisone significantly improves response and time to treatment failure, but not long-term outcome in patients with previously untreated mantle cell lymphoma: results of a prospective randomized trial of the German Low Grade Lymphoma Study Group (GLSG). J Clin Oncol. 2005:23(9): 1984–1992.

[712] Campo E, Rule S. Mantle cell lymphoma: evolving management strategies. *Blood.* 2015;125(1):48–55.

Cytotoxic chemotherapy, proteasome inhibitors (PI), immunomodulatory drugs (IMiD), tyrosine kinase inhibitors, and stem cell transplant (both autologous and allogenic stem cell transplant [ASCT, allo-SCT]). According to the applicant, Bruton's tyrosine kinase (BTK) inhibitors, ibrutinib, zanubrutinib, and acalabrutinib, are common third-line therapy used for patients with r/r MCL and have shown to offer improvements over other chemotherapy-based regimens for r/r MCL patients. The applicant performed a literature review and meta-analysis of patients with r/r MCL whose disease had progressed during or following treatment with a BTK inhibitor and found that despite high initial response rates, most patients eventually developed progressive disease.

Therefore, according to the applicant, new therapeutic strategies are needed to improve the prognosis of patients with r/r MCL whose disease has not been effectively controlled with chemo-immunotherapy, stem cell transplant, and BTK inhibitors.

With respect to the newness criterion, the applicant indicated that the FDA approved the Tecartus Biologics License Application (BLA) on July 24, 2020 for the indication of the treatment of adult patients with relapsed/refractory mantle cell lymphoma (MCL). According to the applicant, Tecartus was granted Breakthrough Therapy designation for the treatment of patients with r/r MCL on June 15, 2018 and received Orphan Drug designation in 2016 for the treatment of MCL, acute lymphoblastic leukemia and chronic lymphocytic leukemia. The following ICD–10–PCS codes were established effective October 1, 2020 to identify the administration of Tecartus: XW23346 (Transfusion of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 6) and XW24346 (Transfusion of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 6).

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion for substantial similarity, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Tecartus is the first CAR T-cell immunotherapy indicated for the treatment of r/r MCL. The applicant further asserted that it does not use a substantially similar mechanism of action. The applicant asserts the FDA concluded and approved Tecartus as distinct from YESCARTA® based on differences in the manufacturing process, certain product specifications and impurities, and formulation of the final products. Furthermore, the applicant stated that Tecartus is distinct from currently available CAR T-cell immunotherapies, namely YESCARTA® and KYMRIAH®, because neither prior CAR T-cell therapy is indicated for the treatment of patients with r/r MCL, and other differences include the manufacturing process, certain product specifications and impurities, and the final dose formulation as determined by the FDA. The applicant stated that MCL is a unique subtype of B-cell Non-Hodgkin's Lymphoma (NHL) and is distinct from DLBCL as determined by the 2016 WHO classification. The applicant stated it reviewed data from the FY 2019 100 percent MedPAR Hospital Limited Data Set to obtain a reference of currently available products used in the treatment of r/r MCL. The applicant stated that based on this analysis, available products used in the treatment of r/r MCL included: chemotherapies, PIs, IMiDs, or BTK inhibitors. The applicant described Tecartus as an autologous CAR T-cell immunotherapy, which genetically modifies the patient's own T-cells to target and eliminate tumor cells for the treatment of r/r MCL and asserted that because Tecartus is an autologous CAR T-cell immunotherapy, it does not use the same mechanism of action as other treatments currently used to treat r/r MCL (chemotherapies, PIs, IMiDs, or BTK inhibitors).

To further note the differences between Tecartus's mechanism of action and other available therapies for r/r MCL, the applicant stated that Tecartus represents a unique product that is customized for B-cell malignancies bearing high levels of circulating CD19-expressing tumor cells. Given these genetic modifications and differences, as previously described, the applicant described Tecartus as having a different mechanism of action from existing r/r MCL therapies.

The applicant stated that Tecartus is a distinct cellular product and is produced by a unique manufacturing process customized for B-cell malignancies characterized by circulating tumor cells and is designed to minimize the number of CD19-expressing tumor cells in the final product. The T cells in the leukapheresis product are enriched by positive selection, activated by culturing with anti-CD3 and anti-CD28 antibodies, and then transduced with a retroviral vector containing the anti-CD19 CAR gene. These engineered T cells are then propagated in culture to generate a sufficient number of cells to achieve a therapeutic effect upon infusion back into the patient. The applicant further stated that Tecartus has a different mechanism of action as compared to YESCARTA® given that the European Medicines Agency (EMA) deemed Tecartus and YESCARTA® as different products.

With respect to the second criterion for substantial similarity, whether a product is assigned to the same or a different MS–DRG, the applicant noted that CMS has established the new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapies), effective October 1, 2020, for CAR T-cell therapies. However, the applicant asserted that Tecartus will be uniquely identified by ICD–10–PCS codes different from those used to identify YESCARTA® and KYMRIAH®. As previously noted, under the current coding system, cases reporting the use of Tecartus would be coded with ICD–10–PCS codes XW23346 and XW24346, which are currently assigned to MS–DRG 018, and therefore we believe that cases reporting the use of Tecartus would be assigned to the same MS–DRG as existing CAR T-cell therapies.

With respect to the third criterion for substantial similarity, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant stated that Tecartus is the first and only CAR T-cell immunotherapy indicated for the treatment of r/r MCL which is identified by ICD–10–CM C83.1X, mantle cell lymphoma, unspecified site. The applicant noted that the patients treated by YESCARTA® and KYMRIAH® are not assigned ICD–10–CM diagnosis code C83.1X (Mantle cell lymphoma, unspecified site), as would patients treated with Tecartus. As previously mentioned, the applicant described that MCL results from a malignant transformation of a B lymphocyte in the outer edge of the lymph node follicle. The applicant further stated that diffuse large b-cell lymphoma (DLBCL), which YESCARTA® and KYMRIAH® treat, is defined as a neoplasm of large B cells arranged in a diffuse pattern. The applicant described this distinction as evidence that Tecartus treats a different subtype of NHL, r/r MCL, as compared to other FDA approved CAR T-cell therapies. However, we note that the applicant recognized in its application that MCL and DLBCL patients share

similar clinical presentation of lymphadenopathy, splenomegaly and constitutional symptoms. The applicant also noted that the disease courses for MCL and DLBCL are different given that MCL has a unique molecular pathogenesis. The applicant stated that patients with r/r MCL often present with high levels of circulating tumor cells which are inherent to the disease [713] [714] or due to peripheral mobilization of tumor cells induced by BTK inhibitor therapy.[715] According to the applicant, MCL requires a customized CAR T-cell therapy for B-cell malignancies bearing high levels of circulating CD19-expressing tumor cells in order to provide a functional autologous cellular therapy. Unlike MCL, the presence of circulating tumor cells occurs only rarely in patients with DLBCL.[716]

With respect to the first criterion, the applicant asserted that Tecartus would provide a new treatment option for adult patients with r/r MCL and therefore is not substantially similar to any existing technologies. We note that for FY 2019 (83 FR 41299), CMS approved two CD19 directed CAR T-cell therapies, YESCARTA® and KYMRIAH®, for new technology add-on payments. In regard to the mechanism of action, the applicant acknowledged that Tecartus is a form of CAR T-cell immunotherapy that modifies the patient's own T-cells, as are YESCARTA® and KYMRIAH®. However, the applicant asserted that the manufacturing process used by Tecartus makes the therapy significantly different from YESCARTA®. The applicant further asserted that its unique manufacturing process which includes a T-cell selection step for patients with MCL, ALL, and CLL is distinct from that used for the manufacture of YESCARTA® for the treatment of patients with malignancies characterized by high numbers of circulating tumor types.

Similar to our discussion of the FY 2021 application in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32636–32637), we are concerned as to whether the differences the applicant described in the manufacturing process should be considered a different mechanism of action as compared to previous CAR T-cell therapies. We note, in their review, the FDA identified many similarities between Tecartus and YESCARTA® to include that, ''the YESCARTA® and KTE–X19 final products are very similar and are formulated identically. The same release testing methods are used for both products.'' [717] Further, as Tecartus is also a CD19-directed T-cell immunotherapy for the treatment of patients with an aggressive subtype of NHL, we continue to question whether the differences identified by the applicant would mean that Tecartus does not have a similar mechanism of action to existing CD19-directed CAR T-cell therapies. We are seeking public comment as to whether the differences the applicant described in the manufacturing process should be considered a different mechanism of action, as compared to previous CAR T-cell therapies.

With regard to the third criterion for substantial similarity, though the applicant described differences between MCL and DLBCL, the applicant also stated that patients with MCL and DLBCL share similar clinical presentation of lymphadenopathy, splenomegaly and constitutional symptoms, and they are both subtypes of NHL. We therefore question whether this therapy may involve the treatment of a similar type of disease when compared to existing CAR T-cell therapies.

We are inviting public comments on whether Tecartus is substantially similar to other technologies and whether Tecartus meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file with the FY 2019 Final Rule IPPS Impact File to identify potential cases representing patients who may be eligible for treatment using Tecartus.

The applicant identified claims that reported an ICD–10–CM diagnosis code of ICD–10–CM C83.1X (Mantle cell lymphoma, unspecified site). The applicant stated that claims reporting ICD–10–CM code C83.1X would not involve the use of the other two approved CAR T-cell therapies because those therapies are not used to treat this diagnosis, MCL. As such, the applicant stated that it used C83.1X to identify potential MCL cases and ICD–10–PCS codes XW033C3 and XW043C3 to identify patients receiving CAR T-cell therapy. In its analysis, the applicant identified two sets of cohorts (Primary Cohort and Sensitivity Analysis Cohort) to assess whether this therapy met the cost criterion. The ICD–10–PCS procedure codes listed in the following table were used to identify claims involving chemotherapy and the applicant noted that these were used for both cohorts.

[713] Argatoff LH, et al. Mantle cell lymphoma: a clinicopathologic study of 80 cases. Blood. 1997;89 (6):2067–78

[714] Gu J, et al. Evaluation of peripheral blood involvement of mantle cell lymphoma by fluorescence in situ hybridization in comparison with immunophenotypic and morphologic findings. Mod Pathol. 2004;17 (5):553–60.

[715] Chang BY, et al. Egress of CD19(+)CD5(+) cells into peripheral blood following treatment with the Bruton tyrosine kinase inhibitor ibrutinib in mantle cell lymphoma patients. Blood. 2013;122(14):2412–24.

[716] Muringampurath-John D, et al. Characteristics and outcomes of diffuse large B-cell lymphoma presenting in leukaemic phase. B. J. Haematol. (2012) 158: 608–614

[717] Price G, Reiser J, Salz T. CBER CMC BLA Review Memorandum, BLA #125703, TECARTUS brexucabtagene autoleucel. FDA.

ICD-10-PCS Procedure Codes Describing Chemotherapy	
ICD-10-PCS Code	**Description**
3E03002	Introduction of high-dose interleukin-2 into peripheral vein, open approach
3E03003	Introduction of low-dose interleukin-2 into peripheral vein, open approach
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E03302	Introduction of high-dose interleukin-2 into peripheral vein, percutaneous approach
3E03303	Introduction of low-dose interleukin-2 into peripheral vein, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E04002	Introduction of high-dose interleukin-2 into central vein, open approach
3E04003	Introduction of low-dose interleukin-2 into central vein, open approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E04302	Introduction of high-dose interleukin-2 into central vein, percutaneous approach
3E04303	Introduction of low-dose interleukin-2 into central vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach

The applicant identified two cohorts for these analyses and used two CCRs to account for the cost of their technology. The Primary Cohort included cases with an ICD–10–CM primary diagnosis of MCL, at least one procedure code indicating receipt of chemotherapy, and no ICD–10–PCS procedure codes indicating CAR T-cell therapy. The applicant believed the Primary Cohort most closely aligned with the characteristics and health of r/r MCL patients who would receive Tecartus given that this cohort includes patients with far advanced disease (comparable to the ZUMA–2 study, as discussed later in this section). The Sensitivity Analysis Cohort included patients with the ICD–10–CM principal or secondary diagnosis of MCL, at least one procedure code indicating receipt of chemotherapy, and no ICD–10–PCS procedure codes indicating CAR T-cell therapy. For each cohort, the applicant performed two sub-analyses that varied the CCR used to calculate Tecartus charges: (1) The national pharmacy CCR of 0.187; and (2) the applicant calculated CAR T-cell CCR of 0.314.

According to the applicant, based on the primary diagnosis code and the presence of chemotherapy, these cases signify that the primary reason for hospitalization was treatment of the patient's MCL, including the complications of their advancing disease and chemotherapy-related complications, and resulted in charges and longer lengths of stay believed to be most reflective of the r/r MCL population that is treated by TECARTUS. The applicant added that this group of MCL cases with MCL as a primary diagnosis most closely compares with the characteristics and health resource utilization of r/r MCL patients that will receive TECARTUS. Furthermore, the applicant stated that the cases in the Primary Cohort had higher charges across all categories than the cases with MCL as a secondary diagnosis. The cases with MCL as a primary diagnosis are according to the applicant more reflective of the r/r MCL population as those cases were more likely being treated for the complications of their advancing disease and chemotherapy-related complications. The average length of stay for hospitalizations in the Primary Cohort was 15.1 days. Lastly, in explaining why CAR T-cell MCL cases from FY 2019 were excluded from the cost analysis, the applicant stated that they could not identify specific charges for CAR T-cell therapy, no individual revenue center had charges similar to those expected for CAR T-cell therapy, and there were no CAR T-cell therapy products approved for the treatment of MCL in FY 2019.

The applicant stated that to estimate the CAR T-cell CCR, they obtained the MS–DRG 018 arithmetic mean charge in the AOR/BOR FY 2021 Proposed Rule File released by CMS ($1,387,946). The applicant subtracted non-drug charges for TECARTUS of $201,610 (based on the TECARTUS FY 2021 new technology add-on payment application) from total arithmetic mean charge to estimate CAR T-cell charges (approximately $1,186,336). The applicant then divided a WAC of CAR T-cell therapy of $373,000 by the estimated CAR T-cell charges to estimate a charge-to-cost ratio of 0.314 (CCR = 373,000/1,186,336).

The claim search conducted by the applicant resulted in 267 claims in the Primary Cohort, mapped to 13 MS–DRGs, and 1,100 claims in the Sensitivity Analysis Cohort, mapped to 59 MS–DRGs using the FY 2019 MedPAR Hospital LDS based on the requirements for each cohort outlined by the applicant. The applicant stated that because TECARTUS cases are mapped to MS–DRG 018, the cost criterion analysis utilized the threshold for MS–DRG 018 for all MS–DRGs included in each cohort rather than the MS–DRG specific threshold. The applicant determined an average unstandardized case weighted charge per case of $1,251,126 for the Primary cohort and $1,251,126 for the Sensitivity Analysis Cohort.

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MS-DRGs in Primary Cohort	
MS-DRG	**Description**
840	Lymphoma & Non-Acute Leukemia w MCC
841	Lymphoma & Non-Acute Leukemia w CC
016	Autologous Bone Marrow Transplant w CC/MCC Or T-Cell Immunotherapy
823	Lymphoma & Non-Acute Leukemia w Other Proc w MCC
842	Lymphoma & Non-Acute Leukemia w/o CC/MCC
824	Lymphoma & Non-Acute Leukemia w Other Proc w CC
014	Allogeneic Bone Marrow Transplant
017	Autologous Bone Marrow Transplant w/o CC/MCC
820	Lymphoma & Leukemia w Major O.R. Procedure w MCC
003	Ecmo Or Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w Maj O.R.
004	Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w/o Maj O.R.
821	Lymphoma & Leukemia w Major O.R. Procedure w CC
825	Lymphoma & Non-Acute Leukemia w Other Proc w/o CC/MCC

MS-DRGs in Sensitivity Analysis Cohort	
MS-DRG	**Description**
847	Chemotherapy w/o Acute Leukemia As Secondary Diagnosis w CC
846	Chemotherapy w/o Acute Leukemia As Secondary Diagnosis w MCC
840	Lymphoma & Non-Acute Leukemia w MCC
841	Lymphoma & Non-Acute Leukemia w CC
016	Autologous Bone Marrow Transplant w CC/MCC or T-Cell Immunotherapy
823	Lymphoma & Non-Acute Leukemia w Other Proc w MCC
842	Lymphoma & Non-Acute Leukemia w/o CC/MCC
824	Lymphoma & Non-Acute Leukemia w Other Proc w CC
829	Myeloproliferative Disorders or Poorly Differentiated Neoplasms w Other Procedure w CC/MCC
014	Allogeneic Bone Marrow Transplant
682	Renal Failure w MCC
871	Septicemia or Severe Sepsis w/o Mv >96 Hours w MCC
017	Autologous Bone Marrow Transplant w/o CC/MCC
838	Chemo w Acute Leukemia As Sdx w CC Or High Dose Chemo Agent
820	Lymphoma & Leukemia w Major O.R. Procedure w MCC
808	Major Hematol/Immun Diag Exc Sickle Cell Crisis & Coagul w MCC
809	Major Hematol/Immun Diag Exc Sickle Cell Crisis & Coagul w CC
683	Renal Failure w CC
004	Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w/o Maj O.R.
864	Fever and Inflammatory Conditions
054	Nervous System Neoplasms w MCC
948	Signs & Symptoms w/o MCC
003	Ecmo or Trach w Mv >96 Hrs or Pdx Exc Face, Mouth & Neck w Maj O.R.
825	Lymphoma & Non-Acute Leukemia w Other Proc w/o CC/MCC
175	Pulmonary Embolism w MCC or Acute Cor Pulmonale
813	Coagulation Disorders
853	Infectious & Parasitic Diseases w O.R. Procedure w MCC
189	Pulmonary Edema & Respiratory Failure
603	Cellulitis w/o MCC
180	Respiratory Neoplasms w MCC
870	Septicemia or Severe Sepsis w Mv >96 Hours
394	Other Digestive System Diagnoses w CC
312	Syncope & Collapse
821	Lymphoma & Leukemia w Major O.R. Procedure w CC
674	Other Kidney & Urinary Tract Procedures w CC
837	Chemo w Acute Leukemia as Sdx or w IIigh Dose Chemo Agent w MCC
668	Transurethral Procedures w MCC
091	Other Disorders of Nervous System w MCC
543	Pathological Fractures & Musculoskelet & Conn Tiss Malig w CC
294	Deep Vein Thrombophlebitis w CC/MCC
854	Infectious & Parasitic Diseases w O.R. Procedure w CC
314	Other Circulatory System Diagnoses w MCC
606	Minor Skin Disorders w MCC
641	Misc Disorders of Nutrition, Metabolism, Fluids/Electrolytes w/o MCC
392	Esophagitis, Gastroent & Misc Digest Disorders w/o MCC
827	Myeloprolif Disord or Poorly Diff Neopl w Maj O.R. Proc w CC
253	Other Vascular Procedures w CC
834	Acute Leukemia w/o Major O.R. Procedure w MCC
552	Medical Back Problems w/o MCC
673	Other Kidney & Urinary Tract Procedures w MCC
393	Other Digestive System Diagnoses w MCC
371	Major Gastrointestinal Disorders & Peritoneal Infections w MCC
315	Other Circulatory System Diagnoses w CC
607	Minor Skin Disorders w/o MCC
205	Other Respiratory System Diagnoses w MCC
602	Cellulitis w MCC
025	Craniotomy & Endovascular Intracranial Procedures w MCC
811	Red Blood Cell Disorders w MCC
270	Other Major Cardiovascular Procedures w MCC
071	Nonspecific Cerebrovascular Disorders w CC
273	Percutaneous Intracardiac Procedures w MCC

MS-DRGs in Sensitivity Analysis Cohort	
MS-DRG	Description
826	Myeloprolif Disord or Poorly Diff Neopl w Maj O.R. Proc w MCC
193	Simple Pneumonia & Pleurisy w MCC
867	Other Infectious & Parasitic Diseases Diagnoses w MCC
191	Chronic Obstructive Pulmonary Disease w CC
982	Extensive O.R. Procedure Unrelated to Principal Diagnosis w CC
391	Esophagitis, Gastroent & Misc Digest Disorders w MCC
699	Other Kidney & Urinary Tract Diagnoses w CC
309	Cardiac Arrhythmia & Conduction Disorders w CC
100	Seizures w MCC
662	Minor Bladder Procedures w MCC
186	Pleural Effusion w MCC

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The applicant then removed charges for prior technology. The applicant stated that the cases representing patients who had received chemotherapy, as reflected by the Medicare claims data, would generally not receive both chemotherapy and Tecartus as an inpatient because conditioning chemotherapy would be administered in the outpatient setting before the patient would be admitted for Tecartus infusion and monitoring. Otherwise, the applicant asserted that patients receiving Tecartus would be expected to incur similar charges to those cases in the Medicare claims data for patients with a primary diagnosis of MCL and receiving chemotherapy (Primary Cohort). In its analysis, the applicant noted that in the FY 2019 MedPAR Hospital LDS, charges for chemotherapy drugs were grouped with charges for oncology, diagnostic radiology, therapeutic radiology, nuclear medicine, CT scans, and other imaging services. The applicant believed that removing all radiology charges would understate the cost of adverse event (AE) clinical management for Tecartus patients needed. The applicant found that when using data from the Q4 2017 and Q1 Q3 2018 Standard Analytic files and comparing total chemotherapy charges to total radiology charges, 2 percent of radiology charges were chemotherapy charges, on average. Therefore, instead of removing all radiology charges, the applicant excluded 2 percent of the radiology charge amount to capture the effect of removing chemotherapy pharmacy charges.

The applicant then standardized the charges and applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges (1.13218). For the Primary and Sensitivity cohorts, the applicant performed two sub-analyses that varied the CCR used to calculate Tecartus charges: (1) using the national pharmacy CCR (0.187); and (2) using the CAR T-cell CCR (0.314).

The applicant stated that when comparing the Primary Cohort to the MS–DRG 018 average case-weighed threshold amount (based on the FY 2021 IPPS/LTCH PPS final rule) and using the national pharmacy CCR, the final inflated average case-weighted standardized charge per case of $2,207,969 exceeded the average case-weighted threshold amount of $1,251,126 by $956,843. When using the CAR T-cell CCR, the final inflated average case-weighted standardized charge per case of $1,399,653 exceeded the average case-weighted threshold amount of $1,251,126 by $148,527. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

When conducting the same review to assess cost for the Sensitivity Analysis Cohort, the applicant noted that the sensitivity analysis cohort also meets the cost criterion when compared to the MS–DRG 018 average case-weighted threshold amount (based on the FY 2021 IPPS/LTCH PPS data file thresholds for FY 2022). As reported by the applicant, when using the national pharmacy CCR in the sensitivity analysis cohort the final inflated average case-weighted standardized charge per case of $2,142,149 exceeded the average case-weighted threshold amount of $1,251,126 by $891,023. When using the CAR T-cell CCR in the sensitivity analysis cohort, the final inflated average case-weighted standardized charge per case of $1,333,833 exceeded the average case-weighted threshold amount of $1,251,126 by $82,707. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion. Because the final inflated average case-weighted standardized charge per case for both the Primary Cohort and the Sensitivity Analysis Cohort exceeds the average case-weighted threshold amount for MS–DRG 018, the applicant maintained that the technology meets the cost criterion. As noted in previous discussions, the submitted costs for CAR T-cell therapies vary widely due to differences in provider billing and charging practices for this therapy. Therefore, with regard to the use of this data for purposes of calculating a CAR T-cell CCR we are uncertain how representative this data is for use in the applicant's cost analyses given this potential for variability.

We continue to be interested in public comments regarding the eligibility of CAR T-cell technologies for new technology add-on payments when assigned to MS–DRG 018. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172 and 85 FR 58603 through 58608), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

We invite public comment on whether Tecartus meets the cost criterion based on this proposal.

With respect to the substantial clinical improvement criterion, the applicant asserted that Tecartus represents a new treatment option for an adult patient population unresponsive to, or ineligible for, currently available treatments. The applicant also believes that the use of Tecartus significantly improves clinical outcomes for a patient with r/r MCL as compared to currently available therapies, including BTK inhibitors. The applicant stated that Tecartus provides access to a treatment option for patients with r/r MCL who have not been responsive to first line or second line therapies. The applicant provided further detail regarding these

assertions, referencing the results of a Phase 2 study (Zuma-2) and historical and meta analyses, which are summarized in this section of this rule.

According to the applicant, because no effective standard therapy for subjects with r/r MCL who have progressed following a prior BTK inhibitor therapy exists, ZUMA–2 lacked a comparison arm. The applicant described how a historical control was the only ethical and feasible study design for patients with r/r MCL who had not responded to the most promising therapies available, including BTK inhibitors. Therefore, the historical control was identified from prior studies identified in a meta-analysis of six studies, which included two studies by Martin et al., (2016) and Cheah et al., (2015), and covered 255 subjects. The ORRs in these six studies ranged from 20%–42% with the applicant identifying 26% [718] and 32% [719] for use as their comparator.

According to the Martin et al. (2016) retrospective cohort study referenced by the applicant, the investigators reported best response rate (RR) to ibrutinib was 55% (43% partial response [PR], 12% complete response [CR]), with 35% of patients having a best response of progressive disease. But among patients who received subsequent therapy, local clinicians reported that 13 patients (19%) achieved PR, and 5 (7%) achieved CR. The median overall survival (OS) following cessation of ibrutinib was 2.9 months (95% confidence interval [CI], 1.6–4.9). Of the 104 patients with data available, 73 underwent at least one additional line of currently available treatment after stopping ibrutinib with a median OS of 5.8 months (95% confidence interval [CI], 3.7–10.4).[720]

A second retrospective study by Cheah et al. identified 42 (54%) who had discontinued therapy of 78 patients with MCL who had been treated at MD Anderson Cancer Center between 2011 and 2014. [721] All 42 patients had received ibrutinib with a median number of cycles of 6.5 (range 1—43). Twenty-eight patients (67%) had disease progression as the main reason for therapy discontinuation. Of the 31 patients who experienced disease progression following ibrutinib and underwent salvage therapy, the overall objective response rate (ORR) and complete response rate (CRR) was 32% and 19%, respectively. After a median follow-up of 10.7 (range 2.4–38.9) months from discontinuation of ibrutinib, the median OS among patients with disease progression was 8.4 months and the estimated one-year OS was 22.1% (95% CI 8.3% to 40.2%).

The applicant summarized further studies that featured BTK therapy. Dreyling et al. and Epperla et al. identified ORRs of 20% and 42% respectively while Wang et al. identified an ORR of 29%, CR rate of 14%, and PR rate of 15% and Jaln et al. identified an ORR of 29%, CR rate of 14%, and PR rate of 15%.[722] [723] [724] [725]

To evaluate the effectiveness of Tecartus, the applicant noted it used an ORR comparison of 25%, which was derived from two aforementioned studies (Martin et al. and Cheah et al.) with patients with r/r MCL who progressed on the most predominantly prescribed BTK inhibitor, ibrutinib. The results of these two studies showed a median OS of 5.8 months after receiving at least 1 additional line of currently available therapy to treat r/r MCL. Those who did not receive salvage therapy had a median OS of 0.8 months.[726]

According to the applicant, the ZUMA–2 study of Tecartus is the only pivotal study of CAR T-cell therapy for r/r MCL. ZUMA–2 is a multicenter, open label, Phase 2 study which evaluated the safety and efficacy of Tecartus in patients with r/r MCL that relapsed or are refractory to prior therapy, including BTK inhibitors. The primary endpoint compared the ORR from the study to the ORR 25% historical control at a one-sided alpha level of 0.025. The applicant stated that ZUMA–2 was not designed to compare the efficacy and safety of TECARTUS to BTK inhibitors, and the results of ZUMA–2 are not intended to indicate that TECARTUS should definitively be utilized to replace any existing therapies. Participants were required to have received prior treatment for MCL, no more than five prior regimens, which must have included anthracycline (or bendamustine containing chemotherapy), an anti-CD20 monoclonal antibody and BTK inhibitor. The ZUMA–2 study included 68 subjects treated with Tecartus out of 75 patients enrolled. The safety analysis included a review of all 68 subjects, with the primary analysis of efficacy reviewing the first 60 subjects treated with Tecartus. ZUMA–2 was conducted at 20 sites in the United States and Europe. Of the 60 subjects in the primary analysis set, 59 were from U.S. sites. Of the 68 subjects in the safety analysis set, 62 were from U.S. sites. Among the 68 subjects, the median age was 65 years (range 38–79) and 57 subjects (84%) were male. Additionally, 58 subjects (85%) had stage IV disease. The sample had a median of 3 prior therapies with 55 (81%) having received ≥3 prior therapies. In addition, 43% had relapsed after a prior autologous stem cell transplant (ASCT); the remaining subjects had either relapsed after or were refractory to their last therapy for MCL.

The applicant asserted that the use of Tecartus significantly improves clinical outcomes for a patient population as compared to currently available treatments. The applicant contended that ibrutinib, a BTK inhibitor, is the most common third-line therapy used for patients with r/r MCL [727] [728] and has been shown to offer improvements over other chemotherapy-based regimens for r/r MCL patients. The applicant also referenced a more selective BTK inhibitor, acalabrutinib, which was approved in the US for the treatment of patients with r/r MCL.[729] [730] In registrational trials, the ORR and CRR were 66% and 17%, respectively for ibrutinib, and 81% and 40%, respectively, for acalabrutinib.[731] [732] The

[718] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[719] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

[720] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[721] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

[722] Dreyling M, et al. Ibrutinib versus temsirolimus in patients with relapsed or refractory mantle-cell lymphoma: An international, randomised, open-label, phase 3 study. Lancet. 2016;387(10020):770–8.

[723] Epperla N, et al. Predictive factors and outcomes for ibrutinib therapy in relapsed/refractory mantle cell lymphoma—a ''real world'' study. Hematological Oncology. 2017:1–8.

[724] Wang M, et al. Observational study of lenalidomide in patients with mantle cell lymphoma who relapsed/progressed after or were refractory/intolerant to ibrutinib (MCL–004). J Hematol Oncol. 2017;10:171.

[725] Jain P, et al. Long-term outcomes and mutation profiling of patients with mantle cell lymphoma (MCL) who discontinued ibrutinib. Br J Haematol. 2018a;183:578–87.

[726] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[727] Campo E, Rule S. Mantle cell lymphoma: Evolving management strategies. Blood. 2015;125(1):48–55.

[728] Vose JM. Mantle cell lymphoma: 2017 update on diagnosis, risk-stratification, and clinical management. Am J Hematol. 2017;92(8):806–813.

[729] Kantar Health. CancerMPact® United States. September 2018, v1.2.

[730] Vose JM. Mantle cell lymphoma: 2017 update on diagnosis, risk-stratification, and clinical management. Am J Hematol. 2017;92(8):806–813.

[731] Ibrutinib USPI. Available from: *https://www.imbruvica.com/docs/librariesprovider7/default-document-library/prescribing_information.pdf.*

applicant contended that primary and secondary resistance to BTK inhibitors [733] is common, and subsequent therapies currently available are minimally effective.[734] [735] [736]

Among the 68 patients treated in the ZUMA–2 study, the primary efficacy analysis was conducted after 60 patients had been enrolled, treated, and evaluated for response for six months after the week four disease assessment. Based on the primary analysis of the 60 subjects included in the ZUMA–2 study, there was an ORR of 93% after a single dose of Tecartus (56 of 60 subjects with a 95% CI of 83.8%, 98.2%). The applicant reported that the complete response rate was 67% (40 of 60 subjects with a 95% CI of 53.3%, 78.3%). The applicant noted the ORR of 93% and CR 67% were observed across age groups (94% ages ≥65; 93% ages <65 and, of the 40 subjects achieving CR, 22 subjects were aged ≥65 and 18 were aged <65). The applicant highlighted that the ORR of 93% was significantly higher than the prespecified historical control rate of 25%. Furthermore, the applicant noted that among the 42 subjects who initially had a partial response (PR) or stable disease (SD), 24 subjects (57%) went on to achieve a CR after a median of 2.2 months (range: 1.8 to 8.3 months). Twenty-one subjects converted from PR to CR, and 3 subjects converted from stable disease (SD) to CR.

According to the applicant, the median DOR was not reached with a median follow-up time for DOR of 8.6 months (95% CI: 7.8, 19.6 months) with a median study follow-up of 12.3 months; this result was consistent across age groups. Kaplan-Meier estimates of the progression free survival (PFS) rates at 6 months and 12 months were 77.0% and 60.9%, respectively, and the median PFS was not reached at the median potential follow-up of 12.3 months. Additionally, 57% of all patients and 78% of patients with a CR remained in remission (results consistent across age groups). Furthermore, as reported by the applicant, among the first 28 subjects studied as part of the interim analysis, 43% remained in continued remission without additional therapy at the follow-up period of 27 months (range, 25.3–32.3).

The applicant also conducted an additional analysis of OS among the first 28 subjects (ZUMA–2 interim analysis) who were treated with Tecartus and had a potential follow-up of ≥24 months. Among these subjects, the OS rate estimate at 24 months was 67.9% and the median OS was not reached. In comparison, the Cheah et al. (2015) post-ibrutinib salvage therapy study reported a lower one-year survival rate of 22%. Additionally, among the subjects in CR at month 3 who had the opportunity to be followed to month 12, 90% remained in CR at month 12. The applicant contended that this statistic showcased that early responses to Tecartus are likely indicative of long-term remission after the single infusion of Tecartus. Furthermore, the applicant suggested that a substantial number of patients with r/r MCL treated with Tecartus will achieve a CR, and that this suggests these patients will likely experience a long-term remission after a single infusion of Tecartus. The applicant also noted that these results were consistent across age groups at the time of the primary data analysis cut-off (July 24, 2019). By contrast, the applicant noted that patients with r/r MCL who had prior BTK inhibitor treatment had CR rates ranging from 7–22%. Additionally, the applicant noted that the majority of patients on BTK inhibitor treatment go on to have progressive disease given that the responses achieved with currently available salvage therapies are short lived and have a DOR ranging from 3 to 5.8 months.[737] [738] [739] [740]

With regard to the safety of Tecartus, the applicant argued that the ZUMA–2 study demonstrated a positive benefit-risk of Tecartus over the current therapy options for patients with r/r MCL. The applicant stated that the toxicity profile that is associated with Tecartus therapy can be managed based upon established guidance. The applicant further stated that the risk evaluation and mitigation strategies (REMS) program will ensure that hospitals providing Tecartus therapy are certified so that all who prescribe, dispense, or administer Tecartus are aware of how to manage the risk of cytokine release syndrome (CRS) and neurologic events. However, the applicant notes that patients who were ≥65 years old showed a trend toward a higher incidence of Grade 3 or higher CRS compared to those ≤65 years old. (21% versus 7%). Additionally, all subjects in the ZUMA–2 primary analysis had at least one adverse event (AE), 99% of subjects had at least one AE that was Grade 3 or higher, and 68% of subjects had at least one serious adverse event (SAE). Among all 68 treated patients, the most common Grade 3 or higher AEs were anemia (51%), neutropenia (53%), and leukopenia (41%). Furthermore, CRS occurred in 62 subjects (91%) in the ZUMA–2 safety analysis. Of these, 10 subjects (15%) had Grade 3 CRS or higher. No subject had Grade 5 CRS, according to the applicant. Furthermore, according the applicant, the most common CRS symptoms of any grade were pyrexia, hypotension, and hypoxia. The most common Grade 3 or higher CRS symptoms were hypotension (35 subjects, 51%), hypoxia (23 subjects, 34%), and pyrexia (62 subjects, 91%). No patient in the ZUMA–2 study treated with Tecartus died from CRS.

The applicant mentioned that 43 of the 68 patients (63%) in the ZUMA–2 study also experienced forms of neurologic events. Of these, 15 subjects (22%) had a worst Grade 3 neurologic event, and 6 subjects (9%) had a worst Grade 4 neurologic event. Twenty-two subjects (32%) had serious neurologic events, however, the applicant noted no subject had a Grade 5 neurologic event. The most common neurologic events of any grade were encephalopathy (21 subjects, 31%), confusional state (14 subjects, 21%), and tremor (24 subjects, 35%). Compared with subjects who were <65 years of age, subjects who were ≥65 years of age showed a trend toward a higher incidence of Grade 3 or higher neurologic events (36% versus 24%). The applicant noted that these neurologic events resolved for all but 6 subjects and that among those whose neurologic events had resolved, the median duration was 12 days. Additionally, no patient died from neurologic events.

[732] Acalabrutinib USPI. Available from: *https://www.azpicentral.com/calquence/calquence.pdf#page=1*.

[733] Rule S, et al. Median 3.5-year follow-up of ibrutinib treatment in patients with relapsed/refractory Mantle Cell Lymphoma: A pooled analysis. *Blood* Dec. 2017;130(Suppl 1):151.

[734] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. *Ann Oncol.* 2015;26(6):1175–9.

[735] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. *Blood.* 2016;127 (12):1559–63.

[736] DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials.* 1986;7(3):177–88.

[737] Kochenderfer JN, et al. Lymphoma Remissions Caused by Anti-CD19 Chimeric Antigen Receptor T Cells Are Associated With High Serum Interleukin-15 Levels. *J Clin Oncol.* 2017a;35(16):1803–13.

[738] Kochenderfer JN, et al. Long-Duration Complete Remissions of Diffuse Large B Cell Lymphoma after Anti-CD19 Chimeric Antigen Receptor T Cell Therapy. *Mol Ther.* 2017b;25(10):2245–53.

[739] Gupta S, et al. Recommendations for the design, optimization, and qualification of cell-based assays used for the detection of neutralizing antibody responses elicited to biological therapeutics. *Journal of Immunological Methods.* 2007;321(1–2):1–18.

[740] Davila ML, et al. Efficacy and toxicity management of 19–28z CAR T cell therapy in B cell acute lymphoblastic leukemia. *Sci Transl Med.* 2014;6(224):224ra25.

In response to CMS's concern as discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32646–32647) regarding the generalizability of the findings from ZUMA–2 to the general Medicare population, the applicant stated that the ZUMA–2 study sample is representative of the Medicare population. The applicant stated that 57% of the sample were 65 to 79 years of age, and that MCL predominantly affects older adults, with a median age at diagnosis ranging from 65 to 73.[741] [742] The applicant asserted that the advanced disease characteristics, including Stage IV disease in 85%, bone marrow involvement in 54%, and splenic involvement in 34%, closely align with those observed in the general MCL population where newly diagnosed and previously untreated patients present with stage III/IV disease and commonly exhibit splenomegaly and bone marrow infiltration.[743] The applicant added that the key baseline characteristics of the ZUMA–2 population mirror the r/r MCL Medicare population refractory to BTK inhibitors, including age of study subjects and stage of disease at study initiation. Overall, ZUMA–2 primary results showed that at the time of the analysis cutoff (July 2019), 16 of 68 subjects (24%) had died; 4 deaths occurred >30 days through 3 months after infusion of Tecartus and 12 deaths occurred ≥3 months after infusion of Tecartus. Fourteen of the 16 subjects died as a result of progressive disease and two of the 16 subjects died due to AEs (Grade 5 AE of staphylococcal bacteremia and Grade 5 AE of organizing pneumonia).

Based on the information provided by the applicant, we have several concerns with regard to the substantial clinical improvement criterion. As we noted in the FY 2021 IPPS/LTCH PPS proposed rule, the combined sample size from the literature search and ZUMA–2 study performed by the applicant is relatively small. While the applicant stated that it closely communicated with FDA in the development of the ZUMA–2 study, including in the development of the sample size, we question whether the ZUMA–2 study results would support a determination of substantial clinical improvement given the small sample size. Although the applicant's analysis of the ZUMA–2 study concluded that Tecartus offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we question whether the sample size and research presented in this application support extrapolating these results across the Medicare population.

Relatedly, we have concerns regarding the potential for selection bias and its effects on results from the ZUMA–2 study. Seventy-four patients were enrolled in the trial and underwent leukapheresis, of which Tecartus was successfully manufactured for 71 (96%) and administered for 68 (92%).[744] According to the authors, the primary efficacy analysis was performed among the 60 first treated patients who had at least 7 months of follow up. We also note that the reported ORR among the first 60 is 93% (95% CI 84–98) and the ORR among all 74 patients enrolled is 85%. We have concerns, given the small sample, about the potential effects of selection bias and of patients being selected out of a study on the results of ZUMA–2, which forms the keystone of the applicant's assertions regarding substantial clinical improvement. Further, some research suggests that trials stopped early for benefit overestimate treatment effects [745] [746] [747] and that formal stopping rules do not reduce this bias, particularly in samples less than 500 events or cases.[748] Given the lack of confidence intervals around the ORR among all 74 patients and the potential for the overestimation of treatment effects, it is unclear whether there is sufficient information to determine a substantial clinical improvement.

As noted in the FY 2021 IPPS/LTCH PPS proposed rule, there has not been a direct study completed comparing outcomes of patients with r/r MCL treatment with Tecartus and BTK inhibitors. According to the applicant, ZUMA–2 remains the only study to evaluate patient outcomes after receiving Tecartus for the treatment of r/r MCL, but this study does not include a direct comparison to other existing therapies for r/r MCL. Despite there being no standard of second-line care for r/r MCL patients that failed on previous therapies, according to the applicant, a BTK inhibitor reflects the best currently available therapy for treating r/r MCL.[749]

The applicant's assertions of substantial clinical improvement are based on the ZUMA–2 trial that uses a historical control ORR of 25%. Given that the ORR in the provided literature review of six articles ranges from 20%–42%, and that, according to the applicant, two specific articles were used to develop the pre-specified historical control rate (26% [750] and 32% [751] respectively), it is unclear whether the historical control is appropriate or representative of r/r MCL patients. Furthermore, given that the applicant states that ZUMA–2 was not designed to compare efficacy and safety of Tecartus to BTK inhibitors, we are uncertain whether it would support a determination of substantial clinical improvement.

As noted in the FY 2021 IPPS/LTCH PPS proposed rule, a longer-term analysis of this population is not available to evaluate the overall survival and mortality data. We note that the applicant did conduct an additional analysis of OS among the first 28 subjects (ZUMA–2 interim analysis) which showed an OS rate estimate at 24 months of 67.9% while the median OS was not reached. Additionally, the applicant referenced that all subjects in the ZUMA–2 primary analysis had at least 1 adverse event, and that throughout the course of the ZUMA–2 study, 16 deaths were recorded. However, while the applicant noted only 2 of these 16 deaths were related to adverse events, we remain concerned that further analysis may be needed to evaluate the safety of Tecartus and the longer term effects of the CRS and neurological events associated with the Tecartus therapy.

We are inviting public comments on whether Tecartus meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New

[741] Smith A, et al. Lymphoma incidence, survival and prevalence 2004–2014: sub-type analyses from the UK's Haematological Malignancy Research Network. Br J Cancer. 2015;112(9):1575–84.

[742] Romaguera JE, et al. High rate of durable remissions after treatment of newly diagnosed aggressive mantle-cell lymphoma with rituximab plus hyper-CVAD alternating with rituximab plus high-dose methotrexate and cytarabine. J Clin Oncol. 2005;23(28):7013–23

[743] McKay P, et al. Guidelines for investigation and management of mantle cell lymphoma. Br J Haematol. (2012) 159, 405–426.

[744] Wang M, et al. KTE–X19 CAR T-Cell therapy in relapsed or refractory mantle-cell lymphoma. N Engl J Med. (2020) 382(14): 1331–1342.

[745] Pocock SJ. When (not) to stop a clinical trial for benefit. JAMA 2005;294:2228e30.

[746] Pocock SJ, Hughes MD. Practical problems in interim analyses, with particular regard to estimation. Control Clin Trials 1989;10(4 Suppl): 209Se21S.

[747] Montori VM, Devereaux PJ, Adhikari NK, Burns KE, Eggert CH, Briel M, et al. Randomized trials stopped early for benefit: a systematic review. JAMA 2005;294:2203e9.

[748] Bassler D, Briel M, Montori VM, Lane M, Glasziou P, Zhou Q, et al. Stopping randomized trials early for benefit and estimation of treatment effects: systematic review and meta-regression analysis. JAMA 2010;303:1180e7.

[749] Campo E, Rule S. Mantle cell lymphoma: evolving management strategies. *Blood.* 2015;125(1):48–55.

[750] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. Blood. 2016;127 (12):1559–63.

[751] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. Ann Oncol. 2015;26(6):1175–9.

Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Tecartus.

s. TERLIVAZ® (Terlipressin)

Mallinckrodt Pharmaceuticals submitted an application for new technology add-on payments for TERLIVAZ® (terlipressin) for FY 2022. Per the applicant, TERLIVAZ® is for intravenous use in the treatment of adults with hepatorenal syndrome type 1 (HRS–1). The applicant stated that TERLIVAZ® (Nα-tryglycl-8-lysine-vasopressin) is a pro-drug for the endogenous/natural porcine hormone [Lys8]-vasopressin and a synthetic vasopressin analog derived from the natural/endogenous human hormone [Arg8]-vasopressin.[752] According to the applicant, TERLIVAZ® has greater selectivity for the vasopressin receptors (V1) versus vasopressin receptors (V2) and inhibits portal hypertension with simultaneous reduction of blood circulation in portal vessels.[753] The applicant stated that the V1 receptor mediated vasoconstrictor activity of TERLIVAZ®, particularly in the splanchnic area, results in an increase in effective arterial volume, an increase in mean arterial pressure (MAP), and normalization of endogenous vasoconstrictor systems (renin-angiotensin-aldosterone and sympathetic nervous system) resulting in increased renal blood flow.[754]

The applicant described HRS–1 as a serious, life-threatening condition characterized by development of acute or sub-acute renal failure in patients with advanced chronic liver disease (CLD). The applicant stated that HRS–1 is estimated to affect between 30,000 and 40,000 patients in the U.S. annually [755] [756] and is the leading cause of hospitalizations among all patients with advanced CLD.[757] The applicant asserted that the high mortality and significant rates of HRS–1–related readmissions support the need for better disease awareness and more effective treatment options.[758] [759] [760] The applicant asserted that there are currently no FDA-approved medications available in the US indicated specifically for the treatment of HRS–1,[761] but several agents are used off-label. The applicant stated that in the U.S., the standard of care and initial treatment for HRS–1 is a combination of midodrine and octreotide, which are used off-label.[762] [763] According to the applicant, this combination is concomitantly administered with albumin. The applicant also stated that in patients who are admitted to the ICU, initial treatment with norepinephrine, also used off-label, in combination with albumin is recommended.[764] The applicant stated that the ideal therapy for HRS–1 is improvement of liver function from either recovery of alcoholic hepatitis, treatment of decompensated hepatitis B with effective antiviral therapy, recovery from acute hepatic failure, or liver transplantation.[765] According to the applicant, TERLIVAZ® is approved as the first-line treatment for HRS–1 in European and Asian countries under appropriate marketing authorizations in those countries.[766]

With respect to the newness criterion, the applicant stated that in 2005, a New Drug Application (NDA) filing for TERLIVAZ® was granted Fast Track designation by the FDA and was considered under Priority Review in May 2008, but a Complete Response Letter (CRL) was issued by the FDA in November 2009. A CRL indicates that the review cycle for an application is complete and that the application is not ready for approval (73 FR 39588). The applicant also stated that in 2016, Mallinckrodt Pharmaceuticals and the FDA reached agreement on their trial protocol design and data analysis under the agency's special protocol assessment (SPA) process. In April 2020, the applicant submitted the current NDA application with FDA as a Class 2 resubmission of the original NDA. On July 15, 2020, the Cardiovascular and Renal Drugs Advisory Committee of the FDA voted to recommend approval of the investigational agent TERLIVAZ® to treat adults with HRS–1, but on September 14, 2020, Mallinckrodt received a CRL from the FDA for this NDA. At the time of the development of this proposed rule, TERLIVAZ® had not received FDA marketing authorization. The applicant submitted a request for a unique ICD–10–PCS code to identify the intravenous infusion of TERLIVAZ®.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, there are currently no FDA-approved treatments for HRS–1 that have a mechanism of action of selectivity for vasopressin V1 receptors. The applicant also stated that TERLIVAZ® represents a different compound type, vasoconstrictor class, and mechanism of action than those of currently available off-label treatments for HRS–1. The applicant submitted the following table that compares the mechanism of action for TERLIVAZ® to the mechanism of action for existing technologies used off-label to treat HRS–1 including midodrine, octreotide, and norepinephrine.

[752] Jamil K, Pappas SC, Devarakonda KR. In vitro binding and receptor-mediated activity of terlipressin at vasopressin receptors V1 and V2. J Exp Pharmacol. 2017;10:1–7.

[753] Wong F. Recent advances in our understanding of hepatorenal syndrome. Nat Rev Gastroenterol Hepatol. 2012;9(7):382–391.

[754] Ibid.

[755] Pant C, Jani BS, Desai M, et al. Hepatorenal syndrome in hospitalized patients with chronic liver disease: results from the Nationwide Inpatient Sample 2002–2012. J Investig Med. 2016;64(1):33–38.

[756] Quick Facts. The United States Census Bureau. *https://www.census.gov/quickfacts/fact/table/US/PST045218.* Accessed January 24, 2021.

[757] Allegretti AS, Ortiz G, Wenger J, et al. Prognosis of Acute Kidney Injury and Hepatorenal Syndrome in Patients with Cirrhosis: A Prospective Cohort Study. Int J Nephrol. 2015;2015:108139.

[758] Rice JB, White AG, Galebach P, et al. The burden of hepatorenal syndrome among commercially insured and Medicare patients in the United States. Curr Med Res Opin. 2017;33(8):1473–1480.

[759] Low G, Alexander GJ, Lomas DJ. Hepatorenal syndrome: Aetiology, diagnosis, and treatment. Gastroenterol Res Pract. 2015;2015:207012.

[760] Angeli P, Bernardi M, Villanueva C, et al. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. J Hepatol. 2018;69(2):406–460.

[761] Jamil K, Huang X, Lovelace B, Pham AT, Lodaya K, Wan G. The burden of illness of hepatorenal syndrome (HRS) in the United States: A retrospective analysis of electronic health records. J Med Econ. 2019;22(5):421–429.

[762] Mindikoglu AL, Pappas SC. New Developments in Hepatorenal Syndrome [published correction appears in Clin Gastroenterol Hepatol. 2018 Jun;16(6):988]. Clin Gastroenterol Hepatol. 2018;16(2):162–177.e1.

[763] Runyon BA. Hepatorenal syndrome. UpToDate.com. *https://www.uptodate.com/contents/hepatorenal-syndrome.* Updated April 13, 2020. Accessed January 26, 2020.

[764] Ibid.

[765] Runyon BA. Hepatorenal syndrome. *UpToDate.com. https://www.uptodate.com/contents/hepatorenal-syndrome.* Updated April 13, 2020. Accessed January 26, 2020.

[766] Sarin S, Sharma P. Terlipressin: An Asset for Hepatologists! Hepatology. 2011;54(2):724–728.

Selected Characteristics Of Drugs Used For The Treatment Of HRS-1				
	TERLIVAZ	**Midodrine[767]**	**Octreotide[768]**	**Norepinephrine[769]**
Compound Type	Vasopressin analogue	α-adrenergic agonist	Somatostatin analogue	α-adrenergic agonist
Vasoconstricor class	Nonsympathomimetic	Sympathomimetic	Sympathomimetic	Sympathomimetic
Receptor binding	V1 vasopressin receptor	α1 receptor	Somatostatin receptor	α1, α2 receptors
Mechanism of action	Selective affinity for vasopressin V1 receptors predominantly located in smooth muscles of arterial vasculature in the splanchnic region. Provides vasoconstrictor and antidiuretic properties to elevate arterial pressure.	Binds to α1 adrenoceptors on peripheral vascular smooth muscle, promoting smooth muscle contraction.	Used with midodrine to activate α1 adrenergic receptors of the arteriolar and venous vasculature, producing an increase in vascular tone and elevation of blood pressure[770].	Binds to α1 adrenoceptors on peripheral vascular smooth muscle, promoting peripheral vasoconstriction.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that TERLIVAZ® may be assigned to the same MS–DRG as existing technologies currently used to treat HRS–1. In particular, the applicant stated that cases involving the use of Terlivaz® may map to the three MS–DRGs included in Major Diagnostic Category (MDC) 7 (Diseases & Disorders of the Hepatobiliary System & Pancreas); MS–DRG 441—Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with CC; MS–DRG 442—Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis with CC; and MS–DRG 443—Disorders of Liver Except Malignancy, Cirrhosis or Alcoholic Hepatitis without CC/MCC. The applicant stated that although TERLIVAZ® may be assigned to the same MS–DRG when compared with an existing technology, this does not mean that TERLIVAZ® is not new for the purposes of new technology add-on payments because, according to the applicant, the existing technologies are not specifically indicated for the treatment of HRS–1. The applicant stated that none of the current standard-of-care drugs used to treat HRS–1, namely midodrine, octreotide, and norepinephrine are FDA-approved for the treatment of this disease. The applicant referenced the discussion in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49445) of BLINCYTO®, as an example of another technology that was the only FDA-approved product available on the U.S. market to treat the relevant indication, and stated that CMS agreed that eligible cases involving the BLINCYTO technology would map to a different MS–DRG than cases treated with similar technologies. The applicant also stated that the MS–DRG system does not differentiate between patients with HRS and non-HRS conditions that are assigned to the three MS–DRGs included in Major Diagnostic Category (MDC) 7 (Diseases & Disorders of the Hepatobiliary System & Pancreas) and further that the current MS–DRGs do not differentiate between HRS type 1 and type 2. The applicant states that because of this, both TERLIVAZ® and an existing technology used to treat non-HRS conditions of HRS type 2 may be assigned to MS–DRGs 441, 442, and 443.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, TERLIVAZ® will treat the same type of disease but will not treat the same or similar population when compared to existing technologies currently treating HRS–1 in the U.S. The applicant stated that TERLIVAZ® will offer treatment to a new patient population that is a subset of the larger patient population for which TERLIVAZ® will receive an FDA label, if approved, and that this subset includes patients for which existing technologies offer a lower rate of recovery of renal function compared to TERLIVAZ®. The applicant states that while the FDA label for TERLIVAZ® will not be reserved for a subset of the patient population that has been diagnosed with HRS–1 and has failed to respond to standard-of-care treatment options, it does not logically follow that because of this label, TERLIVAZ® will not offer a treatment option to a new patient population.

Based on the applicant's statements as summarized above, the applicant believes that TERLIVAZ® is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. We note that while TERLIVAZ® may address an unmet need because it will be the first treatment indicated specifically for the treatment of HRS–1, the applicant's assertion that TERLIVAZ® involves the treatment of a different patient population on the basis that there is a lower rate of renal function recovery using standard of care treatments does not necessarily support the unmet need for HRS–1 treatment. We are inviting public comments on whether TERLIVAZ® is substantially similar to other technologies and whether TERLIVAZ® meets the newness criterion.

With respect to the cost criterion, the applicant searched the FY 2018 MedPAR dataset for cases reporting the ICD–10–CM code K76.7—Hepatorenal syndrome. The applicant stated that average covered charges were obtained at the provider level and case counts for provider instances with fewer than 11

[767] Midodrine. *Drugs.com. https://www.drugs.com/pro/midodrine.html.* Updated August 1, 2020. Accessed January 25, 2021.

[768] Compound Summary of Octreotide acetate. U.S. National Library of Medicine.

[769] Norepinephrine. *Drugs.com. https://www.drugs.com/ppa/norepinephrine.html.* Updated June 15, 2020. Accessed January 4, 2021.

[770] Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of hepatorenal syndrome: a randomized trial. Hepatology. 2015;62:567–574.

discharges at the MS–DRG level were redacted and replaced with the number 1. The applicant initially identified 2,592 providers and 35,806 cases. The applicant excluded 315 providers and 1,149 cases that were not listed in the Impact File FY 2021 Proposed Rule, as the average charges for these cases/providers could not be standardized. The applicant further stated that there were initially 255 MS–DRGs in the data set. However, three MS–DRGs were not found in FY 2022 New Technology Thresholds file posted with the FY 2021 IPPS final rule and correction notice, and an additional three MS–DRGs were excluded because providers were not listed in the Impact File FY 2021 Proposed Rule. The exclusion of those 6 MS–DRGs resulted in an additional 6 excluded cases. Thus, the final data set for analysis included 34,651 cases spanning across a total of 249 MS–DRGs.

The applicant then presented six analyses with defined cohorts. The applicant considered the following factors in defining the cohorts:

- The applicant explained that, because HRS is not always the primary or admitting diagnosis in cases where ICD–10–CM code K76.7 is present, and that K76.7 is commonly coded to cases such as sepsis, they included cases where HRS is the primary and/or admitting diagnosis code in cohorts 1, 3, and 5 and cases where HRS can be the primary, the admitting, or any secondary diagnosis in cohorts 2, 4, and 6.
- The applicant stated that it filtered out cases without a 2-day minimum length of inpatient stay. Per the applicant, the ICD–10–CM diagnosis code K76.7 covers type 1 and type 2 HRS. The applicant stated that HRS type 1 and type 2 have clinical differentiators that make HRS–1 the condition requiring greater hospital resource utilization to treat. The applicant stated that, to produce a cost threshold calculation for an indication of HRS–1, HRS–2 cases must be redacted from any inpatient case population used to ensure charge averages are not dampened by lower costs to treat cases not described by an HRS–1 indication. The applicant explained that HRS–1 is diagnosed by the exclusion of other causes of acute kidney injury in cirrhotic patients, and that no response to 2 consecutive days of diuretic withdrawal and volume expansion with albumin is one of the diagnostic criteria in patients with cirrhosis. Accordingly, per the applicant, patients who do not fulfill this criterion within 48 hours cannot be considered HRS–1 cases and were excluded from the analysis.
- The applicant also stated that the clinical presentation of HRS–1 means the more serious cases requiring stabilization will be treated in the ICU and other cases will be treated in the general medical ward. The applicant included cases with an ICU indicator for Cohorts 1 and 2, representing serious cases where the patient needed stabilization procedures and/or conditions needing immediate attention. The applicant stated that these could be conditions related to, caused by, or leading to the HRS diagnosis or having no relationship to HRS other than a concurrent presence. The applicant also included cases without an ICU indicator for cohorts 3 and 4 and included all cases without differentiation in ICU utilization for cohorts 5 and 6.

Cohort	Cohort Description	Number of Cases	Number of MS-DRGs
1	ICD-10-CM code - K76.7 primary/admitting, ICU indicator, stays of 2+ days only	759	34
2	ICD-10-CM code - K76.7 any position, ICU indicator, stays of 2+ days only	8,915	197
3	ICD-10-CM code - K76.7 primary/admitting, no ICU indicator, stays of 2+ days only	801	38
4	ICD-10-CM code - K76.7 any position, no ICU indicator, stays of 2+ days only	7,154	210
5	ICD-10-CM code - K76.7 primary/admitting, stays of 2+ days only	1,526	51
6	ICD-10-CM code - K76.7 any position, stays of 2+ days only	15,496	249
		Total: 34,651	

The applicant then removed the charges for the technology being replaced. For analyses 1 and 2, the applicant removed the estimated cost of generic norepinephrine based on HRS–1 dosing regimens from each case, which was $1,699 (AnalySource 2018 U.S. Pricing). For analyses 3 and 4, the applicant removed the estimated cost of midodrine plus octreotide based on HRS–1 dosing regimens from each case, which was $3,391 (AnalySource 2018 U.S. Pricing). For analyses 5 and 6, the applicant removed the estimated cost of generic norepinephrine ($1,699) from ICU cases and the estimated cost of midodrine plus octreotide ($3,391) from non-ICU cases.

Across all analyses, the applicant standardized the charges and applied a 2-year inflation factor of 13.1 percent that the applicant stated was used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges. We note that the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges is 1.13218, which would have increased the inflated charges. The applicant stated that it did not add any charges for and related to the new technology or any charges related to the prior technologies.

In the first analysis, (Cohort 1), the applicant computed a final inflated average case-weighted standardized charge per case of $135,189, which exceeded the average case-weighted threshold amount of $70,629.

In the second analysis, (Cohort 2), the applicant computed a final inflated average case-weighted standardized charge per case of $181,617, which exceeded the average case-weighted threshold amount of $88,445.

In the third analysis, (Cohort 3), the applicant computed a final inflated average case-weighted standardized charge per case of $59,184, which exceeded the average case-weighted threshold amount of $56,994.

In the fourth analysis, (Cohort 4), the applicant computed a final inflated average case-weighted standardized

charge per case of $66,974, which exceeded the average case-weighted threshold amount of $63,976.

In the fifth analysis, (Cohort 5), the applicant computed a final inflated average case-weighted standardized charge per case of $96,783, which exceeded the average case-weighted threshold amount of $63,738.

In the sixth analysis, (Cohort 6), the applicant computed a final inflated average case-weighted standardized charge per case of $132,324, which exceeded the average case-weighted threshold amount of $78,101.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under all analyses, the applicant asserted that the technology meets the cost criterion. However, based on the information provided by the applicant, we have the following concerns regarding the cost criterion. We question whether the analyses conducted by applicant may include MS–DRGs that are defined by other factors and which may or may not be related to the intended indication for TERLIVAZ®. Per the applicant, on average, MS–DRGs 441 and 442, used for disorders of the liver, covered 83.41 percent of cases included in cohorts where HRS is the primary and/or admitting diagnosis code, and may therefore be a more refined representation of current reimbursement for cases of HRS–1. We also note that the applicant identified cases using the FY 2018 MedPAR dataset instead of the FY 2019 MedPAR dataset. We invite public comments on whether TERLIVAZ® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserts that TERLIVAZ® represents a substantial clinical improvement over existing technologies because the use of TERLIVAZ® is associated with a more rapid resolution of the HRS–1 disease process and a reduced rate of mortality compared to placebo, midodrine and octreotide, and norepinephrine. The applicant also stated that the use of TERLIVAZ® is associated with a decreased rate of several subsequent diagnostic or therapeutic interventions, compared with placebo and the overall benefit-risk profile of TERLIVAZ® as a treatment for HRS–1 is favorable.

In support of the claim that the use of TERLIVAZ® is associated with a more rapid resolution of the HRS–1 disease process and a reduced rate of mortality compared to placebo, the applicant submitted a PowerPoint presentation that discussed the results of the CONFIRM study. The CONFIRM study[771] was a randomized (2:1), double-blind, placebo-controlled study comparing TERLIVAZ® to placebo in 300 adult patients, 18 years of age or older with HRS–1 (defined as rapidly progressive worsening in renal function to a serum creatinine (SCr) ≥2.25 mg/dL and meeting a trajectory for SCr to double over 2 weeks). TERLIVAZ® or placebo were administered as a 1 mg IV bolus injection every 6 hours for a maximum of 14 days.

The primary objective of the study was to confirm the efficacy and safety of TERLIVAZ® versus placebo in the treatment of adult subjects with HRS–1 receiving standard of care albumin therapy. The primary endpoint was the incidence of verified HRS reversal, defined as 2 consecutive serum creatinine values ≤1.5 mg/dL at least 2 hours apart, while on treatment by Day 14 or discharge, whichever came first (on treatment defined as up to 24 hours after the final dose of study drug). In order to be counted in the primary endpoint, patients needed to be alive without renal replacement therapy (RRT) for at least 10 days after achieving verified HRS reversal. RRT was defined as any procedure to replace nonendocrine kidney function and included intermittent hemodialysis, ultrafiltration, continuous hemofiltration and hemodialysis, peritoneal dialysis, and other dialysis and filtration techniques. The secondary endpoints and their definitions are listed in the following table. The statistical analysis plan also specified that the secondary endpoints were to be tested using the Hochberg procedure to control the overall type 1 error rate.[772] A sample size calculation was conducted and found that a sample size of 300 subjects would provide approximately 90% power with a two-sided type 1 error rate of 0.05 with a 2:1 randomization and assuming event rates of verified HRS reversal of approximately 28% and 12.5%.

Secondary Endpoints	
Secondary Endpoint[773]	**Definition**
Incidence of subjects with HRS-1 reversal	Percentage of subjects with a SCr value ≤1.5 mg/dL while on treatment by Day 14 or discharge. SCr values after RRT, transjugular intrahepatic portosystemic shunt (TIPS), liver transplant, or open-label vasopressor use were excluded
Durability of HRS-1 reversal	Percentage of subjects with HRS reversal without RRT to Day 30
Incidence of HRS-1 reversal in SIRS (systemic inflammatory response syndrome) subgroup	HRS-1 reversal was defined as percentage of subjects with a SCr value ≤1.5 mg/dL while on treatment by Day 14 or discharge The SIRS subgroup was identified based on meeting ≥2 of the following criteria: white blood cell count 12,000 cells/μL, heart rate >90 bpm, temperature >38°C or 20/min, and bicarbonate level
Incidence of verified HRS-1 reversal without HRS-1 recurrence by Day 30	HRS-1 recurrence was defined as rapidly progressive worsening in renal function to SCr ≥2.25 mg/dL without sustained improvement in renal function at least 48 hours after diuretic withdrawal and beginning of plasma volume expansion with albumin

[771] U.S. Food and Drug Administration. Terlipressin Briefing Document. NDA # 022231. Cardiovascular and Renal Drugs Advisory Committee, July 15, 2020. *https://www.fda.gov/media/139963/download*. Accessed February 17, 2021.

[772] Ibid.

The applicant [773] stated that the incidence of verified HRS reversal was 29.1 percent (n=58) in the TERLIVAZ® (treatment) group and 15.8 percent (n=16) in the placebo (control) group (p=0.012).[774] According to the applicant, the incidence of subjects with HRS–1 reversal was 36.2 percent (n=72) in the treatment group and 16.8 percent (n=17) in the control group (p<0.001). The durability of HRS–1 reversal was 31.7 percent (n=63) in the treatment group and 15.8 percent (n=16) in the control group (p=0.003). The incidence of HRS–1 reversal in SIRS subgroup was 33.3 percent (n=28) in the treatment group and 6.3 percent (n=3) in the control group (p <0.001). According to the applicant, the incidence of verified HRS–1 reversal without HRS–1 recurrence by Day 30 was 24.1 percent (n=48) in the treatment group and 15.8 percent (n=16) in the control group (p=0.092). The applicant also claimed that the overall survival up to Day 90 was higher in responders (subjects who achieved verified HRS reversal or HRS reversal while receiving treatment) than in non-responders (p<0.001) in both the treatment and control groups.[775]

The applicant asserted that the study conducted by Arora et al.[776] supports its claims that the use of TERLIVAZ® is associated with a more rapid resolution of the HRS–1 disease process and a reduced rate of mortality compared to norepinephrine. This study was an open-label, randomized controlled trial conducted as a single-center study in India. The study compared a continuous infusion of TERLIVAZ® and albumin to a continuous infusion of norepinephrine and albumin in the management of HRS-acute kidney injury (AKI) in patients with a diagnosis of acute on chronic liver failure (ACLF). Patients were randomized to receive either TERLIVAZ® or norepinephrine in a 1:1 ratio.[777]

ACLF is a distinct diagnosis where, because of severe acute hepatic injury, a rapid loss of liver function develops in a patient with previous chronic liver disease. In this study, ACLF was defined as an acute hepatic insult manifesting as jaundice (serum bilirubin ≥5 mg/dL) and coagulopathy (international normalized ratio [INR] ≥1.5) complicated within 4 weeks by ascites and/or encephalopathy in a patient with previously diagnosed or undiagnosed chronic liver disease or cirrhosis. HRS–AKI was defined as ICA–AKI stage ≥II when other causes of AKI were excluded and the patient was nonresponsive to volume expansion with intravenous albumin.

A total of 120 patients were randomized and 60 patients were allocated to the intention to treat group for both the TERLIVAZ® and norepinephrine arms. Adverse events requiring discontinuation of the drug were reported in 9 of 60 (15%) patients in the TERLIVAZ® arm compared to 5 of 60 (8.3%) in the norepinephrine arm (P=0.39). These events included diarrhea, abdominal pain, atrial fibrillation, cyanosis, and chest pain in the TERLIVAZ® arm. In the norepinephrine arm, patients experienced the previously mentioned adverse events as well as ventricular premature complex (VPCs) and hypertension. The per protocol analysis included 51 patients in the TERLIVAZ® arm and 55 patients in the norepinephrine arm. A response rate of 56% for TERLIVAZ®, a response rate of 43% for norepinephrine, and a 10% noninferiority margin was assumed. For an alpha level of 5 percent and power of 80 percent, it was determined that 57 patients were needed in each arm.

According to the applicant, the results showed that a higher percentage of patients achieved HRS reversal at day 14 (primary endpoint) in the TERLIVAZ® group compared to the norepinephrine group in both the intention to treat analysis (ITT) and per-protocol analysis (PPA) (ITT 40 percent (n=24) vs. 16.7 percent (n=10); p=0.004; PPA 43.13 percent (n=22) vs. 16.3 percent (n=9); p=0.002). Complete response was defined as return of serum creatinine (SCr) to a value within 0.3 mg/dL of baseline.

In support of its claims that TERLIVAZ® is associated with a more rapid resolution of the HRS–1 disease process and a reduced rate of mortality compared to midodrine and octreotide, the applicant summarized the results of the Cavallin et al. study,[778] which compared TERLIVAZ® plus albumin versus midodrine and octreotide plus albumin in a multi-center randomized controlled trial. Patients in the study were from eight hospitals in Italy. The researchers hypothesized a response rate of 60 percent for TERLIVAZ® and of 30 percent for midodrine plus octreotide (MID/OCT), with an alpha error of 5 percent and power of 80 percent. An interim analysis after enrollment of half the sample size set a stopping rule for the randomized clinical trial if the difference in recovery of renal function was significant at P<0.01. The study was terminated after 49 patients were included according to the a priori determined stopping rule. The applicant stated that the results showed that improvement of renal function was significantly more frequent in patients randomized to the TERLIVAZ® group compared to patients randomized to the MID/OCT group; 70.4 percent of patients in the TERLIVAZ® group had a complete or partial response compared with 28.6 percent in the MID/OCT group (p=0.01); 55.5 percent of patients in the TERLIVAZ® group had a complete response compared with 4.8 percent of the MID/OCT group (p<0.001). Complete response was defined as a decrease in serum creatinine to ≤133 µmol/L (≤1.5 mg/dL). Partial response was defined as a ≥50% serum creatinine decrease from baseline to a final value >133 µmol/L (>1.5 mg/dL). No response was defined as a serum creatinine decrease of <50% from baseline.

In this study, some nonresponders to the assigned treatment received a rescue treatment according to the treating physician's decision. Seven of 12 (58.3 percent) nonresponders in the MID/OCT group received a rescue treatment: Six received TERLIVAZ® plus albumin, and one received dialysis. An improvement of renal function was observed in five of six patients (83.3 percent) who received TERLIVAZ® plus albumin. Four patients had a complete response and one patient had a partial response.

In support of its claim that TERLIVAZ® is associated with a decreased rate of subsequent diagnostic or therapeutic interventions, compared with placebo, the applicant cited the results of the CONFIRM trial. The applicant noted that there was a lower incidence of renal replacement therapy through the treatment period (14 days) in patients receiving TERLIVAZ® (23.1 percent (n=46)) versus the placebo (34.7 percent (n=35)). The applicant also stated that there was a decreased incidence of renal replacement therapy (RRT) after liver transplant in patients treated with TERLIVAZ® (19.6 percent

[773] Ibid.

[774] Wong F, Curry MP, Reddy KR, et al, on behalf of the CONFIRM Study Investigators. The CONFIRM Study: A North American Randomized Controlled Trial (RCT) of Terlipressin plus Albumin for the Treatment of Hepatorenal Syndrome Type 1 (HRS–1). Presented at: The American Association for the Study of Liver Diseases (AASLD) meeting; November 8–12, 2019; Boston, MA.

[775] Jamil, K. Terlipressin, a New Investigational Drug for the Treatment of Hepatorenal Syndrome Type 1. Presented at: New Technology Town Hall Meeting; December 16, 2019; Centers for Medicare & Medicaid Services; Baltimore, MD.

[776] Arora V, Maiwall R, Rajan V, et al. Terlipressin Is Superior to Noradrenaline in the Management of Acute Kidney Injury in Acute on Chronic Liver Failure. Hepatology. 2019;71(2):600–610.

[777] Ibid.

[778] Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of hepatorenal syndrome: a randomized trial. Hepatology. 2015;62:567–574.

(n=46)) versus 44.8 percent (n=29) in the placebo group (p=0.04). The applicant stated that the need for RRT post-transplant is predictive of poor graft function and survival.[779] The applicant also claimed that patients receiving TERLIVAZ® stayed an average of 6.4 days in the ICU versus 13.2 days in the placebo group.

In support of its assertion that the overall benefit-risk profile of TERLIVAZ® as a treatment for HRS–1 is favorable, the applicant cited the results of the CONFIRM trial. The applicant noted that the overall incidence of adverse events (AEs) and serious adverse events (SAEs) were similar between patients receiving TERLIVAZ® (n=200) and those receiving placebo (n=99). Further, the applicant stated that 88.0 percent (n=176) of patients receiving TERLIVAZ® reported AEs versus 88.9 percent (n=88) in the placebo group and that 65.0 percent (n=130) of patients receiving TERLIVAZ® reported SAEs versus 60.6 percent (n=60) in the placebo group. The applicant also claimed that the majority of AEs associated with TERLIVAZ® are predictable, recognizable, and generally manageable in the hospital setting where HRS–1 patients are treated.

Finally, the applicant asserted that TERLIVAZ® represents a substantial clinical improvement because the totality of the circumstances otherwise demonstrates that TERLIVAZ® substantially improves, relative to technologies previously available, the treatment of Medicare beneficiaries. The applicant stated that HRS–1 is a serious, life-threatening condition characterized by development of acute or sub-acute renal failure in patients with advanced CLD. The applicant further emphasized that HRS–1 is the leading cause of hospitalizations among all patients with advanced CLD; therefore, inpatient care management of patients with HRS–1 is time and resource intensive, representing a significant cost to hospitals.[780] Finally, the applicant reiterated that upon FDA approval, TERLIVAZ® will be the only FDA-approved drug for the HRS–1 indication that aligns with the European Association for the Study of the Liver (EASL) treatment guidelines for HRS–1: ''Terlipressin plus albumin should be considered as the first-line therapeutic option for the treatment of HRS–AKI.'' [781]

In our assessment of the applicant's claims in support of substantial clinical improvement, we have the following concerns. Regarding the CONFIRM trial, we note that at the time of development of this proposed rule, this study has not been published and we would appreciate access to additional or more robust materials to facilitate further review of the CONFIRM trial results. We note that the proportion of patients with verified HRS reversal without HRS recurrence by Day 30 was numerically greater in the TERLIVAZ® arm, but the difference between groups was not statistically significant (24 percent vs 16 percent, p=0.09) [782] and we note that the potential for HRS–1 recurrence among patients treated with TERLIVAZ® after 30 days is unclear. We also note that, though the applicant claimed a reduction in mortality with the use of TERLIVAZ®, the mortality rate at Day 90 was higher in the TERLIVAZ® group vs the placebo group (51 percent vs 44.4 percent).[783] We further note that the applicant states that survival was not defined as a primary or secondary analysis in the CONFIRM trial and that no overall survival benefit was observed in the CONFIRM trial because survival is confounded by multiple co-morbidities in patients with HRS–1.[784] We note that the primary endpoint of the CONFIRM trial used a surrogate endpoint of serum creatinine as an indicator of HRS reversal, and we question whether this correlates to improvements in clinical outcomes such as mortality and time to transplant. With regard to the applicant's claims regarding a similar incidence of adverse events and serious adverse events between groups in the CONFIRM trial, we note that the results show that the TERLIVAZ® arm had a higher incidence of SAEs up to 30 days post-treatment related to respiratory failure, serious infections such as sepsis and septic shock, GI bleeding, and abdominal pain. Additionally, 61 percent (17⁄28) of respiratory events in the treatment arm were fatal versus 20% (1⁄5) in the placebo arm.[785] Regarding the study conducted by Arora et al., we note that this study had an open-label design and included patients with a diagnosis of ACLF as well as HRS–AKI which may have contributed to the differences observed between the TERLIVAZ® arm and the norepinephrine arm in this study.[786] Finally, we note that the results of the Cavallin et al study submitted by the applicant in support of a substantial clinical improvement over midodrine and octreotide show that there was no survival benefit for the TERLIVAZ® group at months one and three.[787]

We welcome public comment on whether TERLIVAZ® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TERLIVAZ®.

s. VEKLURY® (remdesivir)

Gilead Sciences, Inc. submitted an application for new technology add-on payments for VEKLURY® (remdesivir) for FY 2022. VEKLURY® is a nucleotide analog that inhibits viral RNA-dependent RNA polymerases, demonstrating activity countering viral pathogens such as severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), the virus that causes coronavirus disease 2019 (COVID–19).

According to the applicant, spread of COVID–19 is presumed largely to occur through respiratory droplets and approximately 80% is predicted to occur by pre- and asymptomatic

[779] Watt KDS, Pedersen RA, Kremers WK, et al. Evolution of Causes and Risk Factors for Mortality Post-Liver Transplant: Results of the NIDDK Long-Term Follow-Up Study. Am. J. Transplant. 2010;10(6)1420–1427.

[780] Jamil K, Huang X, Lovelace B, et al. The Burden of Illness of Hepatorenal Syndrome (HRS) in the United States: A Retrospective Analysis of Electronic Health Records. Journal of Medical Economics. 2019;22(5):421–430.

[781] Angeli P, Bernardi M, Villanueva C, et al. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. Journal of Hepatology. 2018;69(2):406–460.

[782] Wong F, Curry MP, Reddy KR, et al, on behalf of the CONFIRM Study Investigators. The CONFIRM Study: A North American Randomized Controlled Trial (RCT) of Terlipressin plus Albumin for the Treatment of Hepatorenal Syndrome Type 1 (HRS–1). Presented at: The American Association for the Study of Liver Diseases (AASLD) meeting; November 8–12, 2019; Boston, MA.

[783] U.S. Food and Drug Administration. Terlipressin Briefing Document. NDA #022231. Cardiovascular and Renal Drugs Advisory Committee, July 15, 2020. *https://www.fda.gov/media/139963/download.* Accessed February 17, 2021.

[784] Mallinckrodt Pharmaceuticals. Terlipressin Briefing Document. NDA #022231. Cardiovascular and Renal Drugs Advisory Committee, July 15, 2020. U.S. Food and Drug Administration. *https://www.fda.gov/media/139965/download.* Accessed February 18, 2021.

[785] U.S. Food and Drug Administration. Terlipressin Briefing Document. NDA #022231. Cardiovascular and Renal Drugs Advisory Committee, July 15, 2020. *https://www.fda.gov/media/139963/download.* Accessed February 17, 2021.

[786] Israelsen M, Krag A, Allegretti AS, et al. Terlipressin versus other vasoactive drugs for hepatorenal syndrome. Cochrane Database Syst Rev [internet] 2017 [cited 2019 Nov 5]; 2017(9). Available from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6483765/.*

[787] Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of hepatorenal syndrome: A randomized trial. Hepatology. 2015;62:567–574.

individuals. The applicant asserted viral incubation averages 3–7 days and can occur for up to 2 weeks.[788] According to the applicant, once infected, approximately 81% of COVID–19 patients experience mild disease, 14% experience severe disease, and 5% experience critical disease.[789] The applicant stated that severity of disease changes with age—approximately 113 in 100,000 people aged 18–49 years are hospitalized, compared to 250 in 100,000 aged 50–64 years and 451 in 100,000 aged 65+.[790] The applicant asserted that other risk factors for severity include underlying comorbidities but severe illness can occur in otherwise healthy individuals at any age.[791]

According to the applicant, patients who present to the hospital with evidence of pneumonia may require supplemental oxygen in severe cases, or, those with critical illness may develop hypoxemic respiratory failure, acute respiratory distress syndrome, and multiorgan failure that requires ventilation support.[792] The applicant cited one study of 2,482 hospitalized COVID–19 patients, in which 32% of patients were admitted to the intensive care unit (ICU) for a median stay of 6 days and 19% received invasive mechanical ventilation, 53% of whom died in the hospital.[793]

According to the applicant, VEKLURY® received FDA approval for use in the inpatient setting on October 22, 2020 via Priority Review and had received Fast Track designation.[794] Under the New Drug Application (NDA) FDA approval, VEKLURY® is indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID–19 requiring hospitalization.[795] [796] Prior to its approval, on May 1, 2020, VEKLURY® received an Emergency Use Authorization (EUA) from FDA for the treatment of suspected or laboratory-confirmed COVID–19 in adults and children hospitalized with severe disease.[797] VEKLURY® continues to have an EUA for pediatric patients (12 years of age or younger weighing at least 3.5 kg or weighing 3.5 kg to less than 40 kgs) for emergency use to treat suspected or laboratory-confirmed COVID–19 in hospitalized pediatric patients.[798] [799]

According to the applicant, VEKLURY® has been available under the EUA since it was first issued in May 2020 for emergency use in the inpatient setting for patients with COVID–19. The applicant asserted that between July 1, 2020 and September 30, 2020, it entered into an agreement with the U.S. Government to allocate and distribute commercially-available VEKLURY® across the country.[800] The applicant stated that under this agreement, the first sale of VEKLURY® was completed on July 10, 2020. The applicant stated that they transitioned to a more traditional, unallocated model of distribution as of October 1, 2020.

According to the applicant, as of August 1, 2020, VEKLURY® is uniquely identified by ICD–10–PCS codes XW033E5 (Introduction of remdesivir anti-infective into peripheral vein, percutaneous approach, new technology group 5) and XW043E5 (Introduction of remdesivir anti-infective into central vein, percutaneous approach, new technology group 5). Prior to August 1, 2020, the generic, non-COVID–19 ICD–10–PCS codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) could be reported for the use of VEKLURY®.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted VEKLURY® is a SARS–CoV–2 nucleotide analog RNA polymerase inhibitor, and that there are no other antiretroviral therapies that have received an EUA or an approval from FDA to treat COVID–19. The applicant stated, however, that convalescent plasma has also received an EUA for the treatment of hospitalized patients with COVID–19.[801] [802] According to the applicant, convalescent plasma is collected from individuals who have been infected with SARS–CoV–2 and have developed antibodies to the virus. The applicant stated that plasma is transfused into infected patients with the expectation that the antibodies present will neutralize the virus.[803] The applicant asserted this mechanism of action is different from VEKLURY® which works as a nucleotide analog to inhibit viral replication. We note that, as a result of their evaluation of the most recent information available, on February 4, 2021 FDA reissued the EUA for convalescent plasma. The EUA authorizes only the use of high titer COVID–19 convalescent plasma, for the treatment of hospitalized patients early in the course of disease. The use of low titer COVID–19 convalescent plasma is not authorized under the EUA.[804]

[788] Cascella M, Rajnik M, Cuomo A, et al. Features, Evaluation, and Treatment of Coronavirus (COVID–19). StatPearls, published August 10, 2020. *https://www.ncbi.nlm.nih.gov/books/NBK554776/.*

[789] McIntosh K, Hirsch MS (ed), and Bloom A (ed). Coronavirus disease 2019 (COVID–19): Clinical features. UpToDate, updated September 14, 2020. *https://www.uptodate.com/contents/coronavirusdisease-2019-covid-19-clinical-features.*

[790] Centers for Disease Control and Prevention (CDC). COVIDView A weekly Surveillance Summary of U.S. COVID–19 Activity, published September 11, 2020. *https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.*

[791] McIntosh K, Hirsch MS (ed), and Bloom A (ed). Coronavirus disease 2019 (COVID–19): Clinical features. UpToDate, updated September 14, 2020. *https://www.uptodate.com/contents/coronavirusdisease-2019-covid-19-clinical-features.*

[792] Ibid.

[793] Kim L, Garg S, O'Halloran A, et al. Risk Factors for Intensive Care Unit Admission and Inhospital Mortality Among Hospitalized Adults Identified through the US Coronavirus Disease 2019 (COVID–19)-Associated Hospitalization Surveillance Network (COVID–NET). Clinical Infectious Diseases. 2020; ciaa1012, *https://doi.org/10.1093/cid/ciaa1012.*

[794] FDA. FDA News Release: FDA Approves First Treatment for COVID–19, published October 22, 2020. *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19.*

[795] VEKLURY® NDA approval: *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf*; *https://www.fda.gov/media/143189/download.*

[796] FDA. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of VEKLURY® (remdesivir): *https://www.fda.gov/media/137566/download.*

[797] FDA News Release: Coronavirus (COVID–19) Update: FDA Issues Emergency Use Authorization for Potential COVID–19 Treatment. Published May 1, 2020. *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-emergency-use-authorization-potential-covid-19-treatment.*

[798] VEKLURY® EUA: *https://www.fda.gov/media/137564/download.*

[799] FDA News Release: COVID–19 Update: FDA Broadens Emergency Use Authorization for VEKLURY® (remdesivir) to Include All Hospitalized Patients for Treatment of COVID–19, published August 28, 2020. *https://www.fda.gov/news-events/press-announcements/covid-19-update-fda-broadens-emergency-use-authorization-VEKLURY®-remdesivir-include-all-hospitalized.*

[800] Veklury (remdesivir)—ASPR's Portfolio of COVID–19 Medical Countermeasures Made Available as a Licensed Product *https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/Veklury.aspx.*

[801] Convalescent plasma EUA: *https://www.fda.gov/media/141477/download.*

[802] FDA. Emergency Use Authorizations: Drug and Biological Products. 2020. *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.*

[803] Liu STH, Li MH, Baine I, at al. Convalescent plasma treatment of severe COVID–19: A propensity score–matched control study. *Nature Medicine.* 2020. *https://doi.org/10.1038/s41591-020-1088-9.*

[804] FDA reissued the EUA on March 9, 2021. FDA In Brief: FDA Updates Emergency Use Authorization for COVID–19 Convalescent Plasma

Continued

We note that another inpatient treatment for COVID–19, Olumiant® (baricitinib), in combination with VEKLURY®, has received an EUA. Specifically, the EUA for Olumiant®, which should be administered in combination with VEKLURY®, is for the treatment of COVID–19 in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).[805] Olumiant® is a Janus kinase (JAK) inhibitor with prior FDA approval for another indication—the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies.[806]

According to the applicant, because of the rapidly evolving nature of the COVID–19 pandemic, there is not a current standard of care used across hospitals in the United States.

With regard to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant asserted that as there no other antiretroviral therapies for the treatment of patients with COVID–19, VEKLURY® could not be assigned to the same MS–DRG as existing technologies.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant asserted VEKLURY® represents a novel treatment option for patients with COVID–19 who are hospitalized. The applicant stated COVID–19 is a completely separate disease from those caused by other coronaviruses. The applicant asserted severe acute respiratory syndrome (SARS) is caused by the coronavirus SARS–CoV and was first reported in 2003. The applicant stated SARS symptoms were similar to COVID–19 and included high fever, body aches, and mild respiratory symptoms but no treatments specific to SARS–CoV have been developed.[807] According to the applicant, MERS–CoV, the Middle east respiratory syndrome coronavirus, was first identified in 2012 and has some similarities in etiology to SARS–CoV–2 but lacks treatment options.[808]

Based on the applicant's statements as summarized previously, the applicant believes that VEKLURY® is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. We note that although there may not be other antiretrovirals available for the treatment of COVID–19, cases involving VEKLURY® may map to the same MS–DRGs as other treatments for COVID–19. We also note that VEKLURY® may not treat a different disease or patient population as existing treatments for COVID–19, as Olumiant® (administered with VEKLURY®) and convalescent plasma appear to treat the same disease and similar patient population.

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments. Therefore, cases involving hospitalized pediatric patients (12 years of age or younger weighing at least 3.5 kg or weighing 3.5 kg to less than 40 kgs) receiving VEKLURY® for emergency use to treat suspected or laboratory-confirmed COVID–19 would not be eligible for new technology add-on payment, if VEKLURY® is approved for new technology add-on payment for the patient population indicated in its FDA approval.

We refer the reader to our comment solicitation in section II.F.7 of the preamble of this proposed rule regarding how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA.

We also invite public comments on any implications of the distribution agreement described previously with regard to the market availability of VEKLURY® .

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to Reflect New Data, published February 4, 2021. *https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data* and *https://www.fda.gov/media/141477/download.*

[805] Olumiant® EUA: *https://www.fda.gov/media/143822/download.*

[806] Olumiant® (baricitinib) [package insert]. FDA, revised July 8, 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/207924s002lbl.pdf.*

[807] CDC. Severe Acute Respiratory Syndrome (SARS), updated December 6, 2017. *https://www.cdc.gov/sars/index.html.*

[808] CDC. About MERS, Updated August 2, 2019. *https://www.cdc.gov/coronavirus/mers/about/index.html.*

We also refer the reader to our proposal in section II.F.8 of the preamble of this proposed rule to extend the new COVID–19 treatments add-on payment (NCTAP) through the end of the fiscal year in which the PHE ends for certain products and discontinue NCTAP for products approved for new technology add-on payments in FY 2022.

We invite public comments on whether VEKLURY® meets the newness criterion.

With regard to the cost criterion, the applicant used the FY 2019 MedPAR LDS and the February through June 2020 Electronic Data Interchange (EDI) transaction data to identify applicable cases. The applicant used the FY 2022 thresholds and the FY 2019 NPRM IPPS/LTCH impact file to standardize charges. As COVID–19 is an emergent disease, the applicant asserted that FY 2019 MedPAR claims may not be reflective of actual cases. Accordingly, and as summarized below, the applicant identified the FY 2019 MedPAR cases as proxy COVID–19 cases in its cost analysis. To supplement and confirm its MedPAR findings, the applicant used EDI data that includes actual COVID–19 cases from February through June 2020 to capture what the applicant described as true COVID–19 MS–DRG mapping and charges.

For the MedPAR LDS cases, the applicant used B97.29 with a manifestation code (J12.89 or J20.8 or J40 or J22 or J98.8 or J80). According to the applicant, this is based on the CDC guidance which specifies use of B97.29 with additional coding to identify the manifestation prior to the April 1, 2020 COVID–19 code. The applicant developed 3 sensitivity scenarios to further differentiate the MedPAR cases; Scenario 1: All Proxy COVID–19, Scenario 2: Proxy COVID–19 without ventilation, and Scenario 3: Proxy COVID19 with ventilation. Next, the applicant analyzed linked 837 and 835 inpatient EDI transaction sets that were processed February through June of 2020. The 837 and 835 transaction sets are updated daily and stored in the Inovalon provider research datasets, accounting for approximately 5–7% of the total Medicare FFS volume nationally on average. For cases prior to April 1, the applicant used the same coding as the MedPAR analysis. For claims on or after April 1, 2020, the applicant used the actual COVID–19 code U07.1. The applicant then identified cases using the 3 sensitivity scenarios; Scenario 4: All COVID–19, Scenario 5: COVID–19 without ventilation, and Scenario 6: COVID–19 with ventilation.

The claim search conducted by the applicant identified 1,726 cases mapping to 25 MS–DRGs for scenario one, 274 cases mapping to eight MS–DRGs for scenario two, 1,393 cases mapping to 21 MS–DRGs for scenario three, 3,826 cases mapping to 21 MS–DRGs for scenario four, 859 cases mapping to seven MS–DRGs for scenario five, and 2,917 cases mapping to 14 MS–DRGs for scenario six. The MS–DRGs identified in each scenario are listed in the following tables.

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List of Identified MS-DRGs With Volumes Higher Than 10 Cases For Scenario 1: All Proxy COVID-19	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
193	Simple Pneumonia & Pleurisy with MCC
202	Bronchitis & Asthma with CC/MCC
189	Pulmonary Edema & Respiratory Failure
190	Chronic Obstructive Pulmonary Disease with MCC
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
194	Simple Pneumonia & Pleurisy with CC
191	Chronic Obstructive Pulmonary Disease with CC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Extracorporea
177	Respiratory Infections & Inflammations with MCC
872	Septicemia or Severe Sepsis without Mv >96 Hours without MCC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Periphe
166	Other Resp System O.R. Procedures with MCC
203	Bronchitis & Asthma without CC/MCC
205	Other Respiratory System Diagnoses with MCC
682	Renal Failure with MCC
308	Cardiac Arrhythmia & Conduction Disorders with MCC
192	Chronic Obstructive Pulmonary Disease without Cc/MCC
292	Heart Failure & Shock with CC
178	Respiratory Infections & Inflammations with CC
698	Other Kidney & Urinary Tract Diagnoses with MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 2: Proxy COVID-19 with Ventilation	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis without Mv >96 Hours w MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
189	Pulmonary Edema & Respiratory Failure
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Extracorporea
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Periphe
193	Simple Pneumonia & Pleurisy with MCC
190	Chronic Obstructive Pulmonary Disease with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 3: Proxy COVID-19 without Ventilation	
MS-DRG	**Description**
871	Septicemia or Severe Sepsis without Mv >96 Hours w MCC
193	Simple Pneumonia & Pleurisy w MCC
202	Bronchitis & Asthma with CC/MCC
190	Chronic Obstructive Pulmonary Disease with MCC
194	Simple Pneumonia & Pleurisy with CC
189	Pulmonary Edema & Respiratory Failure
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
191	Chronic Obstructive Pulmonary Disease with CC
872	Septicemia or Severe Sepsis without Mv >96 Hours without MCC
177	Respiratory Infections & Inflammations with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
203	Bronchitis & Asthma without CC/MCC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC
205	Other Respiratory System Diagnoses with MCC
178	Respiratory Infections & Inflammations with CC
292	Heart Failure & Shock with CC
192	Chronic Obstructive Pulmonary Disease without CC/MCC
280	Acute Myocardial Infarction, Discharged Alive with MCC
166	Other Resp System O.R. Procedures with MCC
682	Renal Failure with MCC
308	Cardiac Arrhythmia & Conduction Disorders with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 4: All COVID-19	
MS-DRG	**Description**
177	Respiratory Infections & Inflammations with MCC
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Extracorporea
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Periphe
178	Respiratory Infections & Inflammations with CC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
193	Simple Pneumonia & Pleurisy with MCC
179	Respiratory Infections and Inflammations without CC/MCC
004	Tracheostomy with Mv >96 Hours Or Principal Diagnosis Except Face, Mouth and Neck without Major O.R.
194	Simple Pneumonia & Pleurisy with CC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 4: All COVID-19	
MS-DRG	**Description**
377	Gastrointestinal Hemorrhage with MCC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
682	Renal Failure with MCC
981	Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC
291	Heart Failure & Shock with MCC or Peripheral Extracorporeal Membrane Oxyg
480	Hip and Femur Procedures Except Major Joint with MCC
637	Diabetes with MCC
689	Kidney and Urinary Tract Infections with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
698	Other Kidney & Urinary Tract Diagnoses with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 5: COVID-19 and Ventilation	
MS-DRG	**Description**
870	Septicemia or Severe Sepsis with Mv >96 Hours or Peripheral Ecmo
207	Respiratory System Diagnosis with Ventilator Support >96 Hours or Peripheral Ecmo
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
177	Respiratory Infections & Inflammations with MCC
004	Tracheostomy with Mv >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R.
853	infectious & Parasitic Diseases with O.R. Procedure with MCC

List of Identified MS-DRGs with Volumes Higher Than 10 Cases for Scenario 6: COVID-19 without Ventilation	
MS-DRG	**Description**
177	Respiratory Infections & Inflammations with MCC
871	Septicemia or Severe Sepsis without Mv >96 Hours with MCC
178	Respiratory Infections & Inflammations with CC
193	Simple Pneumonia & Pleurisy with MCC
179	Respiratory Infections and Inflammations without CC/MCC
194	Simple Pneumonia & Pleurisy with CC
640	Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes with MCC
682	Renal Failure with MCC
377	Gastrointestinal Hemorrhage with MCC
291	Heart Failure & Shock w MCC or Peripheral Ecmo
637	Diabetes with MCC
195	Simple Pneumonia & Pleurisy without CC/MCC
689	Kidney and Urinary Tract Infections with MCC
853	Infectious & Parasitic Diseases with O.R. Procedure with MCC

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The applicant determined an average unstandardized case weighted charge per case of $56,643 for Scenario 1; $82,733 for Scenario 2; $51,100 for Scenario 3; $75,891 for Scenario 4; $131,004 for Scenario 5; and $59,393 for Scenario 6.

The applicant stated that 33 percent of the length of stay charges from relevant cases were removed as charges for and related to the prior technologies in order to estimate the potential decrease in length of stay achieved by use of VEKLURY®. The applicant stated that these length of stay charges were removed from relevant cases to conservatively estimate the potential reduction in charges due to decreased length of stay through use of VEKLURY®. The applicant asserted that this offset was determined based on findings from the Adaptive COVID–19 Treatment Trial (ACTT–1), which found those treated with VEKLURY® had a median recovery time of 10 days, as compared with 15 days for those who received placebo.

After calculating the average standardized charge per case for all scenarios, the applicant calculated the standardized charge per case for each MS–DRG. Next, for the analysis involving MedPAR, the applicant indicated that it applied the 2-year inflation factor used in the FY 2021 IPPS/LTCH PPS final rule to calculate outlier threshold charges of 13.1 percent. We note that the inflation factor used in the FY 2021 IPPS/LTCH PPS final rule was 13.2 percent (1.13218) (85 FR 59039), which would have increased the inflated charges. For the analysis involving the EDI, the applicant used an inflation factor of 1.06353 or 6.4%, which it indicated was the same inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039). We note that the inflation factor used in the FY 2021 IPPS/LTCH PPS final rule was 6.4% (1.06404) (85 FR 59039), but this does not affect the cost analysis. To calculate the charges for the technology, the applicant used the national average CCR for the Drugs cost center of 0.187 from the FY 2021 Final IPPS rule. Lastly, the applicant calculated the case-weighted threshold amount and the final inflated average case-weighted standardized charge per case for each scenario.

The applicant stated that for Scenario 1, the final inflated average case-weighted standardized charge per case of $69,741 exceeded the average case-weighted threshold amount of $56,643 by $13,098. For Scenario 2, the final inflated average case-weighted standardized charge per case of $107,860 exceeded the average case-weighted threshold amount of $82,733 by $25,127. For Scenario 3, the final inflated average case-weighted standardized charge per case of $60,749 exceeded the average case-weighted threshold amount of $51,100 by $9,649. For Scenario 4, the final inflated average case-weighted standardized charge per case of $110,553 exceeded the average case-weighted threshold amount of $75,891 by $34,662. For Scenario 5, the final inflated average case-weighted standardized charge per case of $203,406 exceeded the average case-weighted threshold amount of $131,004 by $72,402. For Scenario 6, the final inflated average case-weighted standardized charge per case of $63,915

exceeded the average case-weighted threshold amount of $59,393 by $4,522.

The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, VEKLURY® meets the cost criterion.

We invite public comment on whether VEKLURY® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that VEKLURY® represents a substantial clinical improvement over existing technologies because it shortens time to recovery in patients hospitalized with severe COVID–19. The applicant also asserted that it represents a substantial clinical improvement because the technology results in improved clinical status and a trend toward reduced mortality, with the most significant reduction seen in a post-hoc analysis of patients with COVID–19 on low-flow oxygen treated with VEKLURY®. The applicant further asserted VEKLURY® results in better clinical status for patients hospitalized with moderate COVID–19.

As stated above, the applicant asserted that VEKLURY® represents a substantial clinical improvement over existing technologies because it shortens time to recovery in patients hospitalized with severe COVID–19. To support this claim, the applicant referenced published, peer-reviewed results from the ACTT–1 study, a multi-center, multi-country adaptive, double-blinded, placebo-controlled, randomized clinical trial. Patients with confirmed COVID–19 and evidence of lung involvement were randomly assigned to receive either VEKLURY® (n=532; 200 mg loading dose on day 1, followed by 100 mg daily for up to 9 additional days) or placebo (n=516) for up to 10 days. Patients could receive other treatments if a participating hospital had a written policy or guideline for treating COVID–19. The study was conducted in 60 trial sites across the world with a majority of trial sites within the United States (45 trial sites plus 13 sub-sites within the United States). The other sites were in Denmark (8), the United Kingdom (5), Greece (4), Germany (3), Korea (2), Mexico (2), Spain (2), Japan (1), and Singapore (1). The primary outcome measure of the ACTT–1 study was time to recovery, defined as the first day, from the time of enrollment into the study, that patients exhibited improvement in conditions based on hospitalization activity limitation, oxygen requirement, and medical care requirement.[809]

According to the applicant, as part of the trial design, an interim analysis was planned to determine if the study should be stopped early for futility, efficacy, or safety, if there was clear and substantial evidence of a treatment difference between study drug and placebo. An independent data and safety monitoring board met to review interim data and determined VEKLURY® was better than a placebo for the primary endpoint, time to recovery.[810] The applicant stated those treated with VEKLURY® had a median recovery time of 10 days, as compared with 15 days for those who received placebo (rate ratio for recovery, 1.29; 95% confidence interval [CI], 1.12 to 1.49; P<0.001), and the number of serious adverse events was lower in the VEKLURY® treated group.[811]

As stated previously, the applicant asserted VEKLURY® represents a substantial clinical improvement over existing technologies because use of VEKLURY® results in improved clinical status and reduced mortality in patients with COVID–19 on low-flow oxygen. According to the applicant, the pivotal ACTT–1 study showed an overall trend toward reduction in mortality with the most significant reduction observed in a post-hoc analysis of patients on low-flow oxyen treated with VEKLURY®. The overall mortality effect was not statistically significant. The applicant stated those treated with VEKLURY® continued to receive oxygen for fewer days (median, 13 days vs. 21 days) and the incidence of new oxygen use was lower in the VEKLURY® group (incidence, 36%; 95% CI, 26% to 47%) compared with the placebo group (incidence, 44%; 95% CI, 33% to 57%). In the post-hoc analysis, those receiving low-flow supplemental oxygen (that is, not those receiving noninvasive ventilation or high-flow oxygen, nor those receiving invasive mechanical ventilation or ECMO) treated with VEKLURY® had the largest reduction in mortality compared to the same cohort receiving the placebo (hazard ratio, 0.30; 95% CI, 0.14 to 0.64).[812]

As stated previously, the applicant asserted VEKLURY® results in better clinical status for patients hospitalized with moderate COVID–19. To support this claim, the applicant referenced published, peer-reviewed results from an open label, placebo controlled, randomized clinical trial. Patients with moderately severe COVID–19 (pulmonary infiltrates on imaging but oxygen saturation >94 percent on room air) were randomly assigned to receive either VEKLURY® plus continued standard of care for 10 days (n=197), VEKLURY® plus continued standard of care for 5 days (n=199), or continued standard of care (n=200). Standard of care could include use of concomitant medications such as steroids, hydroxychloroquine/chloroquine, lopinavir-ritonavir, tocilizumab, and azithromycin. The median time to start VEKLURY® treatment was 8 days after start of symptoms. The median length of treatment in the 10-day group was actually 6 days. Patients who improved could be discharged from the hospital before completing their assigned course of treatment. The study was conducted in 105 trial sites in the United States, Europe and Asia. The primary end point was assessment of clinical status on day 11 after initiation of treatment. Clinical status was assessed on a 7-point ordinal scale ranging from death (category 1) to discharged (category 7).[813]

According to the applicant, on day 11, patients with moderate COVID–19 treated with VEKLURY® for 5 days had a better clinical status compared with the standard of care (odds ratio 1.65; 95% CI, 1.09 to 2.48, P=0.02). The applicant stated the difference was not statistically significant between those treated with VEKLURY® for 10 days compared with the standard of care (P=0.18 by Wilcoxon rank sum test; the proportional odds assumption was not met for this comparison). The applicant asserted that post hoc analyses demonstrated improved clinical status in both the 5- and 10-day treated cohorts at 14 days (P=.03 for both groups). The applicant stated there were no significant differences in adverse events for those treated with Veklury for 5 days.[814]

We note that the articles submitted by the applicant in support of substantial

[809] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid-19—Final Report. *N Engl J Med.* 2020.

[810] The National Institutes of Health (NIH). NIH clinical trial shows Remdesivir accelerates recovery from advanced COVID–19, published April 29, 2020. *https://www.nih.gov/news-events/news-releases/nih-clinical-trial-shows-remdesivir-accelerates-recovery-advanced-covid-19.*

[811] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid-19—Final Report. *N Engl J Med.* 2020.

[812] Ibid.

[813] Spinner CD, Gottlieb RL, Criner GJ, et al. Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID–19 A Randomized Clinical Trial. *JAMA.* 2020; 342(11):1048–1057.

[814] Ibid. Spinner CD, Gottlieb RL, Criner GJ, et al. Effect of Remdesivir vs Standard Care on Clinical Status at 11 Days in Patients With Moderate COVID–19 A Randomized Clinical Trial. *JAMA.* 2020; 342(11):1048–1057.

clinical improvement used study designs that may be subject to bias, such as the adaptive and open label design. The ACTT–1 study included a prespecified interim analysis as part of its adaptive design but no changes were made to the placebo arm. We are unclear whether this may suggest that VEKLURY® did not demonstrate superiority over the control. We also note the ACTT–1 study showed considerable differences between geographic regions in median time to recovery for patients assigned to VEKLURY® compared to those assigned to placebo. For example, for the patient population studied at U.S. sites, the median time to recovery in the VEKLURY® group (n=310) vs. the placebo group (n=271) was 11 days vs. 16 days, respectively, whereas at non-US sites, patients treated with VEKLURY® (n=89) vs. placebo (n=81) experienced a median time to recovery of 8 vs. 12 days, respectively.[815] Furthermore, the ACTT–1 study allowed other simultaneous treatments based on individual hospital policies or guidelines, which may have potentially confounded the results of the trial.

We are inviting public comments on whether VEKLURY® meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for VEKLURY®.

Comment: The applicant responded to questions elicited by its presentation at the New Technology Town Hall Meeting held in December 2020.

First, the applicant was asked to provide information on adverse events and readmissions specifically in patients over 65 years with co-morbidities. The applicant stated that in the pivotal ACTT–1 study, the incidence of overall adverse events was similar among participants ≥65 years of age in both the VEKLURY® and placebo groups (VEKLURY® 65.6%; placebo: 69.7%).[816] The applicant asserted that reported clinical experience has not identified differences in responses between patients over 65 years old and patients under 65 years old and no dosage adjustment is required in patients over the age of 65 years. The applicant stated the NDA for VEKLURY® notes that ''appropriate caution should be exercised in the administration of Veklury and monitoring of elderly patients, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.'' [817] According to the applicant, subanalyses of readmission rates among participants who were at least 65 years of age with comorbidities have not been conducted because the overall rate of readmission is too low for any subanalyses to be meaningful. The applicant stated that in the ACTT–1 study overall, readmittance was reported in 26 participants (5%) in the VEKLURY® group and in 15 participants (3%) in the placebo group.

Second, the applicant was asked to comment on findings of the World Health Organization (WHO)-sponsored SOLIDARITY trial. According to the applicant, the SOLIDARITY trial is an ongoing, multi center, open-label global trial that was designed to (1) provide access to treatments that the WHO expert groups recommended for mortality studies and (2) collect in-hospital mortality data from a large number of participants without posing a significant burden on overstressed healthcare systems. The applicant stated that the trial prioritizes broad access to investigational treatments, particularly in countries where ongoing trials of these treatments were not available, resulting in significant heterogeneity in trial adoption, implementation, controls, and patient populations.

According to the applicant, interim results from the WHO study were published in the *New England Journal of Medicine* (NEJM) on December 2, 2020.[818] The applicant stated that between March 22, 2020 and October 4, 2020, 11,330 adult participants were enrolled at 405 hospitals in 30 countries with vastly different healthcare systems. Of these, 2,743 participants were treated with VEKLURY® and 2,708 were designated as the VEKLURY® control group (received local standard of care only without placebo). The primary endpoint of mortality at Day 28 was 12.5% in the VEKLURY® group and 12.7% in the standard of care group (Kaplan-Meier rate ratio: 0.95 [95% CI: 0.81 to 1.11; p=0.50]). The authors also reported progression to ventilation and time to discharge as secondary endpoints. At the time of the interim analysis, 11.9% in the VEKLURY® group and 11.5% in the standard of care group had progressed to mechanical ventilation and there were no differences between the VEKLURY® and standard of care groups in time to discharge. None of the three drugs evaluated definitively reduced mortality (overall or in any subgroup), initiation of ventilation, or duration of hospitalization.

The applicant stated concerns that the data from WHO's open-label global trial has limitations in light of the trial design. According to the applicant, the variations in the clinical settings of some countries may result in heterogeneity in local standards of care, access to earlier care, or access to mechanical ventilation, which could account for the high observed mortality rate in ventilated patients in SOLIDARITY. Additionally, the applicant stated that lack of detail on the level of oxygen support (low versus high), duration of symptom onset prior to randomization, and the number of VEKLURY® doses administered precludes subanalyses that could elucidate subpopulations who derived benefit from VEKLURY® treatment. Consequently, according to the applicant, it is unclear what conclusive findings can be drawn from the study results at this time.

The applicant stated that according to a perspective piece by Rubin, et al., the FDA approval for VEKLURY® was based on robust evidence from three pivotal studies, including the randomized, double-blind, placebo-controlled ACTT–1 study. The applicant stated that in the opinion of Rubin, et al., the results of SOLIDARITY were not inconsistent with the results of ACTT–1 and any apparent inconsistencies arose from differences in the designs and purposes of the studies. The applicant asserted that the authors of the perspective piece stated that the effect of VEKLURY® appears to be on the course of hospitalization rather than on mortality.[819]

According to the applicant, an editorial by Harrington, et al. indicated that the authors consider it likely that the estimated treatment effects on mortality that were observed in SOLIDARITY are largely accurate given the size of the SOLIDARITY study; however, aspects of the study design that allowed for the rapid execution of the study undermine the ability of the

[815] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid-19—Final Report. *N Engl J Med.* 2020. See Supplementary Table S6.

[816] Ibid. Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid–19—Final Report. *N Engl J Med.* 2020.

[817] VEKLURY® NDA approval (re-issued): *https://www.fda.gov/media/143189/download.*

[818] WHO Solidarity Trial Consortium. Repurposed Antiviral Drugs for Covid–19—Interim WHO Solidarity Trial Results. *NEJM.* December 2, 2020. *https://www.nejm.org/doi/full/10.1056/NEJMoa2023184.*

[819] Rubin D, Chan-Tack K, Farley J, Sherwat A. FDA approval of remdesivir—a step in the right direction. *N Engl J Med.* DOI: 10.1056/NEJMp2032369.

study to evaluate more subtle endpoints, such as time to recovery.[820]

The applicant noted that treatment guidelines from the US National Institute of Health and the Infectious Disease Society of America, which have been updated since publication of the interim data from the SOLIDARITY study, continue to recommend treatment with VEKLURY® in hospitalized patients who require supplemental oxygen. Further, the applicant asserted, these efficacy and safety data have supported regulatory approvals or temporary authorizations to treat COVID–19 in approximately 50 countries worldwide.

Third, the applicant was asked to provide more information on the evidence showing there was a trend towards lower mortality, notably in patients who received low flow oxygen. The applicant stated that in the overall ACTT–1 population, there was a numerical trend toward lower mortality in the VEKLURY® group (11.4%) compared to the placebo group (15.2%), which did not reach statistical significance (p=0.07).[821] The applicant asserted that a post-hoc analysis of participants receiving low-flow supplemental oxygen (baseline ordinal scale score of 5), revealed that VEKLURY® reduced mortality by 70% compared with placebo (4.0% vs. 12.7%; hazard ratio: 0.30 [95% CI: 0.14 to 0.64]).

Lastly, the applicant was asked to provide more information to justify the claim that all subgroups consistently improved with VEKLURY®, given that Medicare patients are older and frequently have co-morbidities. According to the applicant, across the clinical spectrum, hospitalized patients with COVID–19 receiving VEKLURY® recovered 5 days faster, on average, than those receiving placebo (10 days vs. 15 days; rate ratio: 1.29; 95% CI: 1.12–1.49; p<0.001), representing an increased recovery rate of 29%.[822] The applicant stated that this clinically meaningful benefit is observed across subgroups, including among participants at least 65 years of age.

Response: We appreciate the applicant's responses to questions asked at the New Technology Town Hall Meeting and will take this information into consideration when deciding whether to approve new technology add-on payments for VEKLURY®.

u. ZEPZELCA™ (lurbinectedin)

Jazz Pharmaceuticals submitted an application for new technology add-on payments for ZEPZELCA™ for FY 2022. According to the applicant, ZEPZELCA™ is an alkylating drug indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. ZEPZELCA™ is a marine-derived, synthetic antineoplastic compound that inhibits transcription-dependent replication stress and genome instability in tumor cells.

According to the applicant, small cell lung cancer (SCLC) is an aggressive type of lung cancer where patients that progress after first-line chemotherapy have a poor prognosis due to limited clinical benefit from currently available second-line chemotherapy. Patients relapsing or progressing more than 90 days after completion of first-line treatment are considered platinum sensitive and may be rechallenged with platinum-based chemotherapy.[823] The majority of SCLC treated patients show disease relapse and are eligible for second-line therapy; however, few second-line treatment options exist.[824]

According to the applicant, lung cancer overall is the second most common malignancy in the United States with 234,030 new cases and 154,050 deaths estimated in 2018.[825] Per the applicant, where most lung cancers are classified as non-SCLC, SCLC now comprises approximately 15% of all lung cancers. According to the applicant, SCLC is the most aggressive form of lung cancer characterized by rapid disease progression and early metastatic spread [826] [827] [828]—doubling in cell number about every 30 days and spreading quickly to lymph nodes and other organs.[829] The applicant stated that the Veterans Lung Cancer Study Group used a two-stage system for describing SCLC, with a limited-stage (30% of cases) which is confined to a smaller portion of the body, and an extensive-stage (70% of cases) where the tumor was widespread.[830] [831] Many patients with SCLC have substantial comorbidities that may affect performance status and treatment options.[832] A restrospective review analysis of Extensive-stage SCLC (ES–SCLC) patients found that when compared to patients at diagnosis, patients receiving second-line therapy were more likely to have congestive heart failure (67% vs 49%), thromboembolism (9% vs 2%), and depression (11% vs 7%).[833] Further, these patients receiving second-line therapy were more likely to have infectious disease (57% vs 43%), electrolyte disorders (50% vs 22%), anemia (45% vs 19%), neutropenia (17% vs <0.2%), thrombocytopenia (12% vs 2%), and diarrhea (7% vs 3%) compared to the incidence of these comorbidities at diagnosis of ES–SCLC.[834]

According to the applicant, the standard of care for first-line chemotherapy for both limited-stage SCLC and ES–SCLC is platinum doublet and, in the case of ES–SCLC, platinum doublet in combination with a checkpoint inhibitor. SCLC is sensitive to platinum-based chemotherapy in the first-line setting but almost universally relapses, requiring subsequent lines of therapy.[835] [836] [837] Once a patient

[820] Harrington David P., Baden Lindsey R., Hogan Joseph W. (2020) A Large, Simple Trial Leading to Complex Questions. *N Engl J Med* DOI: 10.1056/NEJMe2034294.

[821] Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid–19—Final Report. *New England Journal of Medicine* 2020.

[822] Ibid.

[823] Garassino MC, et al. Outcomes of small-cell lung cancer patients treated with second-line chemotherapy: A multi-institutional retrospective analysis. *Lung Cancer* 72 (2011) 378–383.

[824] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045.*

[825] Tan WT, et al. Small Cell Lung Cancer (SCLC), Medscape, Oncology. Updated June 19, 2020. Emedicine.medscape.com.

[826] *Ibid.*

[827] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. *Medical Oncology* (2018) 35:61.

[828] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[829] Surveillance, Epidemiology, and End Results Program (SEER). Cancer stat facts: lung and bronchus cancer. *https://seer.cancer.gov/statfacts/html/lungb.html.* Accessed September 2020.

[830] *Ibid.*

[831] PDQ Adult Treatment Editorial Board. PDQ small cell lung cancer treatment. Bethesda, MD: National Cancer Institute. Updated March 20, 2020. *https://www.cancer.gov/types/lung/hp/small-cell-lung-treatment-pdq.* Accessed March 22, 2020. [PMID: 26389347].

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[833] Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

[834] Ibid. Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

[835] Shao C, et al. Chemotherapy treatments, costs of care, and survival for patients diagnosed with small cell lung cancer: A SEER-Medicare study. *Cancer Med.* 2019;8:7613–7622.

[836] He J, et al. Survival, chemotherapy treatments, and health care utilization among patients with advanced small cell lung cancer: An observational study. *Adv Ther.* 2020;37:552–565.

[837] Karve SJ, et al. Comparison of demographics, treatment patterns, health care utilization, and costs

Continued

relapses, the likelihood of response is highly dependent on time from initial therapy to relapse,[838] with survival based on the duration of remission.[839] According to the applicant, ES–SCLC is incurable; patients are treated with palliative intent, with a median survival of 7 to 11 months after diagnosis and with less than 5% survival at 2 years.[840] [841] Even limited-stage disease is rarely cured with radical local therapy (surgery or radiotherapy), and systemic chemotherapy (platinum plus etoposide) remains the cornerstone of first-line treatment in SCLC.[842] Despite best management, the 5-year overall survival (OS) of even limited-stage SCLC is still only 15% to 25%.[843] [844]

The applicant asserted that while SCLC shows high sensitivity to first-line chemotherapy and radiotherapy, most patients develop disease relapse or progression within one year of treatment.[845] [846] [847] It is reported that about 80% of limited-disease SCLC patients and almost all patients with ES–SCLC will develop relapse or progression after first-line treatment. Without second-line chemotherapy, the median survival time is 2 to 4 months.[848] [849] The applicant stated that for patients classified as sensitive to first line treatment, due to remaining relapse-free for at least 3 months after treatment, rechallenge with the same chemotherapy regimen given as first line treatment is reasonable. For those classified as refractory (disease progression through first line treatment) and resistant (patients who show initial response to treatment but whose disease progresses within 3 months of completing chemotherapy), the second line treatment is Hycamtin (topotecan). According to the applicant, topotecan was the only preferred agent in the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for second-line treatment of patients with a Chemotherapy-free Interval (CTFI) <6 months. In summarizing the evidence of topotecan efficacy, the applicant stated that studies showed a median survival of 6.8 to 7.8 months,[850] [851] [852] progression free survival of 2.7 to 3.5 months,[853] [854] [855] and a median time to progression of 13.3 weeks.[856] Furthermore, the applicant asserted that topotecan is associated with hematological toxicities such as anemia, neutropenia, thrombocytopenia, and febrile neutropenia.[857] [858] [859]

The applicant stated that since topotecan's approval in 1998, no other second-line SCLC treatment option had been approved until ZEPZELCA™ gained approval in June 2020. According to the applicant, ZEPZELCA™ is the first second-line treatment option for SCLC since 1998.

According to the applicant, the FDA approved ZEPZELCA™ on June 15, 2020 under the FDA's Accelerated Approval Program with Priority Review. ZEPZELCA™ was also granted Orphan Drug Designation by the FDA. ZEPZELCA™ is administered intravenously as a 3.2 mg/m^2 dose over one hour, repeated every 21 days until disease progression or unacceptable toxicity. ZEPZELCA™ will typically be administered in an outpatient clinic. However, per the applicant, because many patients with SCLC have substantial comorbidities that may necessitate hospitalization and initiation of treatment, the first infusion and possibly some additional infusions will be administered in the inpatient

among elderly patients with extensive-stage small cell and metastatic non-small cell lung cancers. *BMC Health Serv Res.* 2014;14:555.

[838] Shao C, et al. Chemotherapy treatments, costs of care, and survival for patients diagnosed with small cell lung cancer: A SEER-Medicare study. *Cancer Med.* 2019;8:7613–7622.

[839] Pietanza MC, et al. Small cell lung cancer: Will recent progress lead to improved outcomes? *Clin Cancer Res.* 2015;21(10):2244–2255.

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[842] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: A single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045.*

[843] Simos D, et al. Third-line chemotherapy in small-cell lung cancer: An international analysis. *Clin Lung Cancer* (2014) 15 (2): 110–8.

[844] Pelayo AM, et al. Chemotherapy versus best supportive care for extensive small cell lung cancer. *Cochrane Database Syst Rev* (2013) 11: CD001990.

[845] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. *Medical Oncology* (2018) 35:61.

15437.

[846] Shiozawa, T. Rechallenge with first-line platinum chemotherapy for sensitive-relapsed small-cell lung cancer. *Case Rep Oncol.* 2018;11:622–632.

[847] Horita N, et al. Topotecan for relapsed small-cell lung cancer: Systematic review and meta-analysis of 1347 patients. *Sci Rep* 2015;5: 15437.

[848] Shiozawa, T. Rechallenge with first-line platinum chemotherapy for sensitive-relapsed small-cell lung cancer. *Case Rep Oncol.* 2018;11:622–632.

[849] Wakuda K et al. Efficacy of second-line chemotherapy in patients with sensitive relapsed small-cell lung cancer. *In vivo.* 33:2229–2234 (2019).

[850] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: Phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

von Pawel J TopotecanTopotecancyclophospham idecyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent. *J Clin*VolVol 17, No 2, 1999: 658–667.

[851] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[852] Von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[853] vonVon Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: Phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[854] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[855] von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: Phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[856] vonVvon Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[857] vonvVon Pawel J.

Evans TL, et al. CabazitaxelRandomized phase III trial of amrubicinCabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35. sensitive relapsed small-cell lung cancer: Phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[858] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[859] Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: Phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

hospital setting.[860] The applicant stated that there are no existing ICD–10–PCS codes that uniquely identify the administration of ZEPZELCA™. The applicant submitted a request for a unique ICD–10–PCS code to identify the technology beginning FY 2022.

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the mechanism of action of ZEPZELCA™ is not the same or similar to the mechanism of action of currently available products used in the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. Per the applicant, ZEPZELCA™ is a novel synthetic antineoplastic marine derived compound with a unique mode of action and chemical structure, with a terminal half-life of 51 hours and total plasma clearance of 11 L/h (50%).[861] [862] According to the applicant, ZEPZELCA™ is a transcription inhibitor that binds DNA preferentially in quinine-rich sequences located within gene regulatory elements and induces a rapid degradation of transcribing RNA polymerase II that induces the eviction of oncogenic transcription factors and the silencing of their transcription program. The applicant states that ZEPZELCA™ has preclinical data which suggests that oncogenic transcription of DNA to RNA was selectively inhibited via the dual actions of RNA polymerase II degradation and the formation of DNA breaks, which leads to apoptosis.[863] The applicant further states that ZEPZELCA™ has been shown to induce immunogenic cell death,[864] and based on preclinical data, impacts the tumor microenvironment by altering the survival of tumor-associated macrophages (TAMs) and the production and function of key oncogenic inflammatory and growth factors.[865]

According to the applicant, topotecan is a semi-synthetic derivative of camptothecin with topoisomerase I-inhibitory activity that relieves torsional strain in DNA by inducing reversible single strand breaks. The pharmacokinetics of topotecan have been evaluated in cancer patients following doses of 0.5 to 1.5 mg/m^2 administered as a 30-minute infusion. Topotecan exhibits multiexponential pharmacokinetics with a terminal half-life of 2 to 3 hours. Total exposure area under the curve (AUC) is approximately dose proportional.[866] The applicant asserts that a clinical differentiator of ZEPZELCA™ from topotecan is the rate of hematologic adverse reactions including neutropenia, anemia, thrombocytopenia, and febrile neutropenia.[867] [868] [869]

Lastly, the applicant asserted that ZEPZELCA™ is not substantially similar to the more recently approved first-line treatments for ES–SCLC, TECENTRIQ® (atezolizumab) and IMFINZI® (durvalumab), both of which are PD–L1 blocking antibodies.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that ZEPZELCA™ will not map to MS–DRGs distinct from other treatments for SCLC.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant stated that there have been no approved treatments for second-line treatment of SCLC since 1998 when topotecan was approved. Topotecan is indicated for the treatment of small cell lung cancers in patients with chemotherapy-sensitive disease after failure of first-line chemotherapy.[870] The applicant states that topotecan is approved for relapses at least 60 days after initiation of a platinum-containing first-line regimen. ZEPZELCA™ is indicated for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.[871] The applicant also stated that ZEPZELCA was listed as a preferred regimen by the NCCN Clinical Practice Guidelines for second-line treatment of patients with a chemotherapy free interval (CTFI) ≤6 months and recommended for patients with a CTFI >6 months.[872]

The applicant repeated results concerning the efficacy of topotecan and asserted that the efficacy results were achieved with a high rate of grade three and four hematologic Treatment Emergent Adverse Events (TEAEs).

In summary, the applicant asserted that ZEPZELCA™ meets the newness criterion because its mechanism of action is not the same or similar to the mechanism of action of currently available products used in the treatment of adult patients with metastatic SCLC and because it is indicated in patients with disease progression on or after platinum-based chemotherapy.

We are inviting public comments on whether ZEPZELCA™ is substantially similar to an existing technology and whether it meets the newness criterion.

With respect to the cost criterion, the applicant conducted the following analysis to demonstrate that ZEPZELCA™ meets the cost criterion. For the primary cost analysis cohort the applicant used the selection criteria of the presence of a lung cancer code as defined by ICD–10–CM family C34 (Malignant neoplasm of bronchus and lung) as the principal diagnosis and the presence of any chemotherapy code as

[860] Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

[861] ZEPZELCA website, ZEPZELCA™ prescribing information., Rev. 6/2020: *https://www.zepzelcapro.com/*.

[862] Romano M. et al. Travectedin and lurbinectedin are effective against leukemic cells derived from patients affected by chronic and juvenile myelomonocytic leukemia. *European Journal of Cancer.* 50 (6 Suppl):48.

[863] Santamaria G, et al. Lurbinectedin reverses platinum dependent IRFI overexpression and nuclear localization, partially responsible for resistance to platinum drugs in ovarian cancer. *Proceedings of the American Association for Cancer Research* (2017) 58:311.

[864] Xie W, et al. Lurbinectedin synergizes with immune checkpoint blockade to generate anticancer immunity. *Oncoimmunology.* 2019;5;8(11):e1656502.

[865] Farago AF, et al. ATLANTIS: A phase III study of lurbinectedin/doxorubicin versus topotecan or cyclophosphamide/doxorubicin/vincristine in patients with small-cell lung cancer who have failed one prior platinum-containing line. *Future Oncol.* 2019;15(3):231–239.

[866] FDA website, Hycamtin (topotecan) prescribing information., Rev. 2/2014: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022453s002lbl.pdf*.

[867] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[868] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[869] Monnet I, et al. Carboplatin-etoposide versus topotecan as second-line treatment for sensitive relapsed small-cell lung cancer: Phase 3 trial (ID 546) IASLC. 2019 World Conference on Lung Cancer; Barcelona, Spain; September 7–10, 2019 (abstr OA15.02).

[870] FDA website, Hycamtin (topotecan) prescribing information., Rev. 2/2014: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022453s002lbl.pdf*.

[871] ZEPZELCA website, ZEPZELCA™ prescribing information., Rev. 6/2020: *https://www.zepzelcapro.com/*.

[872] NCCN Clinical Practice Guidelines in Oncology, Small Cell Lung Cancer. Version 4.2020, July 7, 2020. *https://nccn.org*.

defined by ICD_10–CM Z51.11 (Encounter for antineoplastic chemotherapy), ICD–10–CM Z51.12 (Encounter for antineoplastic immunotherapy), or any ICD–10–PCS chemotherapy code. Additionally, the applicant performed three sensitivity analyses for the cost criterion. The first is a broad cohort with the selection criteria of the presence of at least one lung cancer code (C34xx) and the presence of any chemotherapy code as defined by ICD–10–CM code Z51.11 (Encounter for antineoplastic chemotherapy), Z51.12 (Encounter for antineoplastic immunotherapy), or any ICD–10PCS chemotherapy code. The second and third analyses involved TECENTRIQ® and IMFINZI® which are both immunotherapy drugs that have FDA approval for use as part of the first-line treatment in patients with SCLC. These drugs are to be used along with chemotherapy. The second analysis is the ''TECENTRIQ®'' cohort with the selection criteria of the presence of at least one lung cancer code (C34xx) as either the principal or admitting diagnosis, and excluding cases with any ES–SCLC surgical codes. The final analysis, the ''IMFINZI®'' cohort, has the selection criteria of at least one of the following: (1) Presence of at least one lung cancer code (C34xx) and presence of any platinum-based chemotherapy code as defined by ICD–10–CM Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.12 (Encounter for antineoplastic immunotherapy); (2) Presence of at least one lung cancer code (C34xx) and assigned to MS–DRGs for respiratory neoplasms (180–182). The applicant stated that ZEPZELCA™ is supplied in 4 mg single-dose vials with the recommended dose of 3.2 mg/m² by intravenous infusion over 60 minutes every 21 days until disease progression or unacceptable toxicity. Based on clinical study, the applicant stated that a single dose of ZEPZELCA™ ranged from 4.05 mg to 6.4 mg. To identify cases that may be eligible for the use of ZEPZELCA™, the applicant searched the FY 2019 MedPAR LDS file using these cohort selection criteria. The applicant stated that in all analyses, they imputed a case count of 11 for MS–DRGs with fewer than 11 cases and calculated the weighted average standardized charges across all MS–DRGs.

Based on the FY 2019 MedPAR LDS file, the applicant identified a total of 1,100 cases in the primary cohort (mapped to 17 MS–DRGs), 4,034 cases in the first sensitivity cohort (mapped to 195 MS–DRGs), 34,437 cases in the second sensitivity cohort (mapped to 253 MS–DRGs), and 24,209 cases in the third sensitivity cohort (mapped to 128 MS–DRGs). The applicant utilized the FY 2019 Final Rule with Correction Notice IPPS Impact File. Using the cases identified, the applicant then calculated the unstandardized average charges per case for each MS–DRG. The applicant expects that ES–SCLC patients will receive their initial dose of ZEPZELCA™ in the inpatient setting. The applicant then standardized the charges and inflated the charges by 1.13218 or 13.2 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule. The applicant removed charges associated with chemotherapy since treatment with ZEPZELCA™ would replace chemotherapy. To do so the applicant found the ratio of chemotherapy charges to radiology charges (0.14470075) from claims in the FY 2019 inpatient standard analytic file with a primary diagnosis of lung cancer (ICD–10–CM C34xx) and chemotherapy charges greater than zero. The applicant then added the charges for ZEPZELCA™ by converting the costs of a single treatment (two single-dose vials) to a charge by dividing the cost by the national average cost-to-charge ratio of 0.187 for pharmacy from the FY 2021 IPPS/LTCH PPS final rule. The applicant calculated a final inflated average case weighted standardized charge per case for the primary cohort as $206,030, and $182,895, $146,174, and $130,975 for sensitivity cohorts 1, 2 and 3, respectively. The applicant referred to the FY 2022 New Technology Thresholds data file to determine the average case-weighted threshold amount for the primary cohort as $79,420, and $70,499, $70,226, and $57,383 for sensitivity cohorts 1, 2 and 3, respectively. The final inflated average case-weighted standardized charge per case in the primary cohort and three sensitivity cohorts exceeded the average case-weighted threshold amount by $126,610, $112,396, $75,948, and $73,592 respectively. Because the final inflated average case-weighted standardized charge per case exceeds in all scenarios the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

While we would not expect a significant difference, we note that instead of referring to the correction notice tab within the FY 2022 New Technology Thresholds data file, the applicant referred to the final rule tab. The FY 2022 New Technology Thresholds data file is available on the CMS IPPS home page at: *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2021-ipps-final-rule-home-page#Data*.

We also note that the analysis provided by the applicant includes many MS–DRGs that are defined by factors that may or may not be related to ZEPZELCA™'s indication for metastatic SCLC. For example, it is not clear that MS–DRG 004 Trach w MV >96 Hrs or Pdx Exc Face, Mouth & Neck w/o Maj O.R has a direct connection to small cell lung cancer though it may be related.

We are inviting public comment on whether ZEPZELCA™ meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that ZEPZELCA™ significantly improves clinical outcomes over existing treatment options for adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy in five ways. First, ZEPZELCA™ offers an improved treatment option from both a safety and efficacy standpoint. Second, ZEPZELCA™ offers safety improvement for treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy over safety results previously reported in the literature for a comparable patient population. Third, patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy achieved higher overall response rates (ORRs) following treatment with ZEPZELCA™ than ORR that had been previously reported in the literature for a comparable patient population. Fourth, overall survival (OS) rates achieved with ZEPZELCA™ are clinically meaningful and are the highest rates reported for patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy in more than 2 decades. Fifth, the applicant asserted that ZEPZELCA™ may represent a valuable treatment alternative to platinum rechallenge. The applicant submitted (or in some cases, referred to) multiple sources in support of these claims including retrospective analyses and other studies, a meta-analysis, data abstracts, literature reviews, prescribing information, FDA approved cancer therapies, practice guidelines, workgroup deliberations, a commentary, and an opinion regarding survival outcomes.

With regard to the first claim, the applicant stated that ZEPZELCA™ is the first second-line treatment option approved for SCLC since 1998 and is

indicated for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy, a patient population with dismal outcomes. The applicant also stated that ZEPZELCA™ offers an improved treatment option from both a safety and efficacy standpoint. The applicant outlined the nature of small cell lung cancer, patient treatment and prognosis. The applicant also stated that ZEPZELCA™ could represent a valuable option for a patient population with high unmet medical need.[873] Specifically, the applicant referred to four analyses, an epidemiology review, prescribing information, practice guidelines, a literature review inclusive of four articles, and one ZEPZELCA™ study.

First, an analysis stated that although small cell lung cancer shows high sensitivity to first-line chemotherapy and radiotherapy, most patients develop disease relapse or progression.[874] Another analysis stated that most patients experience relapse of small cell lung cancer within 1 year of treatment.[875] A separate analysis indicated that most patients who have initially responded to chemotherapy and radiotherapy eventually experience recurrence of the cancer in a few months.[876] The fourth analysis indicated that almost all patients with extended disease will develop disease relapse or progression after first-line treatment and that without second-line chemotherapy, the median survival time is 2 to 4 months.[877]

Next, in referring to the epidemiology review, the applicant stated that most cases of small cell lung cancer occur in individuals aged 60–80.[878] In referring to prescribing information, the applicant stated that in 1998, Hycamtin (topotecan) was approved for patients with SCLC sensitive disease after failure of first-line chemotherapy. The applicant further stated that in the topotecan Phase 3 clinical study, sensitive disease was defined as disease responding to chemotherapy, but subsequently progressing at least 60 days after chemotherapy.[879]

Next, in referring to practice guidelines, the applicant stated that ZEPZELCA was studied in a broader (resistant disease and sensitive disease) population of SCLC patients and that prespecified subgroup analyses of ZEPZELCA results were done for patients with SCLC by CTFI in patients with resistant disease (CTFI <90 days) and sensitive disease (CTFI interval ≥90 days). The applicant further noted that NCCN guidelines list ZEPZELCA as a preferred regimen for second-line treatment of patients with a CTFI ≤6 months and recommended ZEPZELCA for patients with a CTFI >6 months.[880]

Next, the applicant referred to a literature review and submitted four sources. First, per the applicant, Iams et. al. describes available data on clinical efficacy, the emerging evidence regarding biomarkers and ongoing clinical trials using immune checkpoint inhibitors and other immunotherapies in patients with SCLC. The article included a discussion of the significant unmet needs in second-line therapy for SCLC.[881] Second, per the applicant, Tsiouprou et. al. reported on a literature review of immunotherapy in treatment of ES–SCLC and included a discussion of the significant unmet needs in second-line therapy for SCLC.[882] Third, per the applicant, Wang et. al. presented a review of SCLC development, current therapy and included a discussion of the significant unmet needs in second-line therapy for SCLC.[883] Fourth, per the applicant, Taniguchi et. al., is an opinion article discussing recent developments in the treatment of SCLC and includes a discussion of the significant unmet needs in second-line therapy for SCLC.[884]

Finally, the applicant referred to Trigo, et. al., and stated that authors expressed that ZEPZELCA could present a valuable potential new treatment option after first-line platinum based chemotherapy.[885]

With regard to the second claim, the applicant asserted that ZEPZELCA™ offers safety improvement for treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy over safety results previously reported in the literature for a comparable patient population. The applicant asserted that safety is of particular importance for patients ≥65 with age being a major patient-related risk factor.[886] The applicant also referred to a meeting abstract stating that several acute comorbidities were more common in Medicare patients initiating second-line chemotherapy than in all patients at diagnosis: Infectious disease (57% versus 43%), electrolyte disorder (50% versus 22%), anemia (45% versus 19%), neutropenia (17% versus 0.1%), thrombocytopenia (12% versus 2%), and diarrhea (7% versus 3%).[887]

The applicant also referred to six studies to support this claim. First, the applicant submitted Trigo et. al., that was based on Study B–005 (NCT01454972), a single-arm, open label, phase II basket trial to evaluate the activity and safety of lurbinectedin in patients with SCLC after failure of platinum-based chemotherapy. One hundred five patients with a diagnosis of SCLC and pre-treated with only one previous chemotherapy-containing line of treatment were included. Treatment consisted of 3.2mg/m2 lurbinectedin intravenously every 3 weeks until disease progression or unacceptable toxicity. The safety-related outcomes demonstrated the following adverse events: Anemia 9%, leucopenia 29%, neutropenia 46%, and thrombocytopenia 7%. Serious treatment-related adverse events occurred in 10% of patients, of which

[873] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: A single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045*.

[874] Shiozawa, T. Rechallenge with first-line platinum chemotherapy for sensitive-relapsed small-cell lung cancer. *Case Rep Oncol.* 2018;11:622–632.

[875] Naito Y, et al. Rechallenge treatment with a platinum-based regimen in patients with sensitive relapsed small-cell lung cancer. *Medical Oncology* (2018) 35:61.

[876] Horita N, et al. Topotecan for relapsed small-cell lung cancer: Systematic review and meta-analysis of 1347 patients. *Sci Rep* 2015;5:15437.

[877] Wakuda K et al. Efficacy of second-line chemotherapy in patients with sensitive relapsed small-cell lung cancer. *In vivo.* 33:2229–2234 (2019).

[878] Tan WT, et al. Small Cell Lung Cancer (SCLC), Medscape, Oncology. Updated June 19, 2020. *Emedicine.medscape.com.*

[879] FDA website, Hycamtin (topotecan) prescribing information., Rev. 2/2014: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/022453s002lbl.pdf*.

[880] NCCN Clinical Practice Guidelines in Oncology, Small Cell Lung Cancer. Version 4.2020, July 7, 2020. *https://nccn.org*.

[881] Iams WT, et al. Immunotherapeutic approaches for small-cell lung cancer. *Nat Rev Clin Oncol.* 2020 May; 17(5):300–312. doi: 10.1038/s41571–019–0316–z. Epub 2020 Feb 13.

[882] Tsiouprou I, et al. The rôle of immunotherapy in extensive stage small-cell lung cancer: A review of the literature. *Can Respir J.* 2019 Nov 3;2019:6860432. doi: 10.1155/2019/6860432. eCollection 2019.

[883] Wang Y, et al. New insights into small-cell lung cancer development and therapy. *Cell Biol Int.* 2020 Aug;44(8):1564–1576. doi: 10.1002/cbin.11359. Epub 2020 Apr 18.

[884] Taniguchi H, et al. Targeted therapies and biomarkers in small cell lung cancer. *Front Oncol.* 2020 May 20;10:741. doi: 10.3389/fonc.2020.00741. eCollection 2020.

[885] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: A single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045*.

[886] Simeone E, et al. Nivolumab for the treatment of small cell lung cancer. *Exp Rev Resp Med.* 2020;14(1):5–13.

[887] Danese M, et al. Comorbidity in patients with extensive disease small cell lung cancer. Presented at the AMCP Managed Care & Specialty Pharmacy Annual Meeting; March 27–30, 2017; Denver, CO.

neutropenia and febrile neutropenia were the most common with 5% of patients for each.[888]

Second, the applicant submitted an article from Von Pawel, et. al., of a randomized phase 3 study of a total of 637 patients with refractory or sensitive SCLC treated with topotecan and reported hematologic toxicities of grade ≥3 anemia, 30.5%; neutropenia, 53.8%; thrombocytopenia, 54.3%; febrile neutropenia, 3%.[889]

Third, the applicant submitted an open label phase 2 study of 179 patients with SCLC who relapsed after initial platinum-based chemotherapy, treated with topotecan and reported hematologic toxicities of neutropenia, 78.4%; thrombocytopenia, 45.5%; and febrile neutropenia/neutropenic infection/neutropenic sepsis, 18%.[890]

Fourth, the applicant submitted an abstract from Monnet, et. al. of an open-label, multicenter, phase 3 trial that randomized patients with SCLC that responded to first-line platin-etoposide doublet treatment but showed evidence of disease relapse or progression at least 90 days after completion of the first-line treatment. Eighty-two patients were assigned to each treatment group: Those receiving combination chemotherapy (carboplatin and etoposide) versus those receiving oral topotecan. The abstract indicated that grade ¾ neutropenia was significantly more common in the topotecan group at 35.8% versus 19.7%; insignificantly more febrile neutropenia in the topotecan arm at 13.6% versus 6.2%; no difference for grade ¾ thrombocytopenia, 35.8% versus 30.9%; and anemia, 24.6% versus 21%.[891]

Fifth, the applicant submitted an abstract from Leary, et. al., that is described as a pooled safety analysis with data from the phase II, single arm basket study by Trigo, et. al. (discussed previously), and a phase III RCT, the CORAIL study. The pooled analysis included a total of 554 patients treated with lurbinectedin. Of the 554, 335 were from the phase II basket study with selected solid tumors (9 indications including 105 patients with small cell lung cancer) and 219 were from the phase III CORAIL study with platinum resistant ovarian cancer. Authors presented an indirect exploratory comparison (pooled data from CORAIL + basket) and a direct comparison (data from CORAIL) of lurbinectedin vs. topotecan. Authors reported adverse events with lurbinectedin were grade ½ fatigue, nausea and vomiting. Treatment-related lurbinectedin/topotecan outcomes showed: Dose reductions: 22.9/48.3%; delays: 25.8/52.9%; grade ≥3 serious adverse events: 15.0/32.2%; discontinuations: 3.2/5.7%; deaths: 1.3/1.5%; granulocyte colony stimulating factor (G–CSF) use: 23.8/70.1%; and transfusions: 15.9/52.9%. Authors concluded by stating that a significant safety advantage was observed when lurbinectedin was compared with topotecan in the CORAIL trial in terms of hematological toxicities. Authors also noted that with the limitations of indirect comparisons, in the pooled safety analysis, fewer lurbinectedin-treated patients had severe hematological toxicities, severe adverse events, dose adjustments, treatment discontinuations and use of supportive treatments than topotecan-treated patients.[892]

Sixth, the applicant provided a presentation summarizing results from the randomized phase 3 CORAIL study. The patient population was comprised of platinum resistant ovarian, fallopian or primary peritoneal cancer. Enrolled patients were randomly assigned to receive lurbinectedin or investigator choice of pegylated liposomal doxorubicin (PLD) or topotecan. The applicant stated that ZEPZELCA™ was better tolerated than the control arm and that, overall, the data support a favorable safety profile for ZEPZELCA™.[893]

With regard to the third claim, the applicant stated that patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy achieved higher ORRs following treatment with ZEPZELCA™ than ORR that had been previously reported in the literature for a comparable patient population. The applicant referred to four primary resources in support of ZEPZELCA™. First, as described previously, the applicant submitted Trigo, et. al., in which the primary endpoint is described as lurbinectedin anti-tumor activity in terms of investigator-assessed overall response (OR) and duration of response (DOR) as a secondary endpoint.[894] The OR rate was identified as 35.2% and the mean DOR as 5.3 months. Second, the applicant submitted an abstract from Subbiah, et. al., a sub-study from Study B–005, that concluded that time from randomization to response was similar regardless of prior resistance or sensitivity to platinum-based chemotherapy, and clinically meaningful DOR was noted in both subgroups of responders.[895] Third, the applicant submitted an abstract from a second sub-study from Study B–005, indicating that ORR was similar across baseline characteristics: Age <65 = 36.8%; age ≥65 = 32.4%; female = 31%; male = 38.1%; 1 prior line of therapy = 34.7%; ≥2 prior lines of therapy = 42.9%; BSA ≤1.8m2 = 34.5%; and BSA >1.8m2 = 36%. The authors concluded by noting that response to lurbinectedin appeared consistent regardless of baseline patient characteristics.[896] Fourth, the applicant submitted a commentary from Arrieta, et. al., and stated that ZEPZELCA™ outperformed all previously reported results for topotecan.[897]

The applicant also referred to three additional sources reflecting ORRs following treatment with topotecan. The Phase 3 trial of a total of 637 patients with refractory or sensitive SCLC treated with topotecan demonstrated an ORR of 16.9% and DOR of 4.2 months.[898] In the open-label, multicenter, phase 3 trial of 164 patients with sensitive relapsed SCLC that responded to first-line platin etoposide doublet treatment but showed evidence of disease relapse or progression at least 90 days after

[888] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: A single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045.*

[889] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[890] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10:1221–1228.

[891] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S.

[892] Leary A, et al. Pooled safety analysis of single-agent lurbinectedin versus topotecan (Results from a randomized phase III trial CORAIL and a phase II basket trial). ASCO2020 (American Society of Oncology); May 29–31, 2020. Abstract and poster.

[893] Gaillard S, et al. Phase III trial of lurbinectedin versus PLD or topotecan in platinum-resistant ovarian cancer patients: Results of the CORAIL trial. 2018 ESMO Presentation.

[894] Additional secondary endpoints are discussed with the overall survival claim.

[895] Subbiah V, et al. Phase 2 basket trial of lurbinectedin in second-line SCLC: Characteristics and outcomes in treatment responders. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[896] Sands J, et al. Phase 2 basket trial of lurbinectedin in small-cell lung cancer (SCLC): Analysis of efficacy by baseline characteristics. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[897] Arrieta O, et al. New opportunities in a challenging disease: lurbinectedin for relapsed small-cell lung cancer. Comment in *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020.*.https://doi.org/10.1016/S1470-2045(20)30097-8.*

[898] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

completion of the first-line treatment, patients randomized to the topotecan group demonstrated an ORR of 25%.[899] Lastly, a randomized, multi-center phase 3 trial of 107 patients treated with topotecan reported an ORR of 24.3%.[900]

With regard to the fourth claim, the applicant stated that the OS rates achieved with ZEPZELCA™ are clinically meaningful and are the highest rates reported for patients with metastatic SCLC whose disease progresses on or after platinum-based chemotherapy in more than 2 decades. The applicant submitted two studies in support of its claim of improved survival rates in patients treated with ZEPZELCA™. First, as described previously, the applicant submitted Trigo, et. al. and highlighted secondary endpoints including progression-free survival, progression-free survival at 4 and 6 months, overall survival and overall survival at 6 and 12 months. The mean progression free survival was identified as 3.5 months, mean overall survival 9.3 months in the overall population, 11.9 months in patients with a CTFI ≥90 days and 5.0 months in those with CTFI <90 days.[901]

Second, the applicant submitted an abstract from Subbiah, et. al., that summarized a sub-study from Study B–005 in which overall survival was a secondary endpoint. Authors report that patients treated with lurbinectedin had CTFI ≥180 days and form the basis for their analysis. Sixty percent of patients were male, had ECOG PS 0–1, and had a median age of 57 years. Extensive stage disease at initial diagnosis was present in 35% of patients. All 20 patients had received prior platinum/etoposide, with no prior immunotherapy. Authors also reported that with a censoring of 55.0%, the median overall survival was 16.2 months. Per the abstract, eleven patients (55.0%) were censored for survival analysis: Eight were on follow-up after disease progression, two were ongoing lurbinectedin treatment, and one had treatment discontinuation because of a treatment-related adverse event (worsening of prior peripheral neuropathy). Median follow-up was 15.6 months. Authors concluded time from randomization to response was similar regardless of prior resistance or sensitivity to platinum-based chemotherapy.[902]

The applicant also referred to several randomized phase I and II studies of patients undergoing alternate therapies and highlighted those OS rates. The applicant provided an abstract from Monnet, et. al., (as mentioned previously with respect to applicant's second and third claims) summarizing results from a study that investigated whether the doublet carboplatin-etoposide was superior to topotecan monotherapy as second-line treatment in patients with sensitive relapsed SCLC. Authors reported patients treated with topotecan had progression free survival (PFS) of 2.7 months and OS of 7.4 months.[903] The applicant also referred to Evans, et. al., summarizing results from a study of patients with SCLC who relapsed after initial platinum-based chemotherapy who were divided into subgroups, chemosensitive vs. chemo-resistant/refractory disease. Patients were treated with topotecan. Authors reported topotecan PFS of 3.0 months and OS of 6.8 months.[904] The applicant referred to Von Pawel, et. al., summarizing the results of a phase 3 trial of a total of 637 patients with refractory or sensitive SCLC, including topotecan PFS of 3.5 months and OS of 7.8 months (5.7 months for refractory).[905] Lastly, the applicant referred to Von Pawel, et. al., that reported randomized, multi-center phase 3 results for topotecan with time to progression of 13.3 weeks and median OS of 25 weeks.[906]

The applicant explained that a statement from an American Society of Clinical Oncology (ASCO) workgroup indicated that relative improvements in median OS of at least 20% are necessary to define a clinically meaningful improvement in outcome.[907] The applicant summarized oncology literature reviews between 2014 and 2016 asserting that ASCO's threshold for OS was met in only 12% of studies (6 of 49) and 19% of therapies.[908] [909]

The applicant further stated that ZEPZELCA™'s median OS for the overall population compared to the literature, meets the ASCO threshold and, for subsets of patient groups, median OS exceeds the ASCO threshold for clinically meaningful.

The applicant concluded by stating that there is an urgent need for new treatment options for the SCLC population.[910] The applicant asserted that CMS's new technology add-on payment approval of TECENTRIQ® for the treatment of patients with ES–SCLC effective for FY 2021 (85 FR 58684) further supports the urgency, referring to its 2 month improvement in survival.

The applicant also referred to comments from specialists in the field of lung cancer stating that despite small trial sizes, improvement in overall survival is a major achievement and that any advance in survival is important given that few patients diagnosed with SCLC survive for even a year despite treatment.[911]

With regard to the fifth claim, that ZEPZELCA™ may represent a valuable treatment alternative to platinum rechallenge, the applicant submitted several sources pertaining to ZEPZELCA™. First, the applicant submitted two sub-analyses from Subbiah, et. al., that were based on Study B–005 as its primary support for ZEPZELCA™. In both of these sub-analyses, patients had been pre-treated with one prior platinum-containing line. The first analysis included 20 patients from a subset of patients with CTFI >180 and authors report that patients

[899] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S

[900] Von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[901] Trigo J, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: A single-arm, open-label, phase 2 basket trial. *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045.*

[902] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[903] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S.

[904] Evans TL, et al. Cabazitaxel versus topotecan in patients with small-cell lung cancer with progressive disease during or after first-line platinum-based chemotherapy. *J Thorac Oncol.* 2015;10: 1221–1228.

[905] Von Pawel J, et al. Randomized phase III trial of amrubicin versus topotecan as second-line treatment for patients with small-cell lung cancer. J Clin Oncol. (2014) 32:35.

[906] Von Pawel J, et al. Topotecan versus cyclophosphamide, doxorubicin, and vincristine for the treatment of recurrent small-cell lung cancer. *J Clin Oncol.* Vol 17, No 2, 1999: 658–667.

[907] Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol.* 2014;32(12:1277–1280).

[908] Dreicer JJ, et al. Clinically meaningful benefit: real world use compared against the American and European guidelines. *Blood Cancer Journal.* 7,10.1038/s41408–017–0009–8.

[909] Kumar H, et al. An appraisal of clinically meaningful outcomes guidelines for oncology clinical trials, *JAMA Oncology*. Published online: Vol 2, No 9, 1238–1240.

[910] NCI Staff. For small cell lung cancer, immunotherapy drug finally brings improved survival. National Cancer Institute. October 3, 2018. *https://www.cancer.gov/news-events/cancer-currents-blog/2018/small-cell-lung-cancer-atezolizumab-survival.*

[911] NCI Staff. For small cell lung cancer, immunotherapy drug finally brings improved survival. National Cancer Institute. October 3, 2018. *https://www.cancer.gov/news-events/cancer-currents-blog/2018/small-cell-lung-cancer-atezolizumab-survival.*

treated with lurbinectedin had an ORR at 60.0% and a median DoR of 5.5 months. The second analysis included 60 patients from a SCLC cohort of the basket trial, with CTFI >90 d (20 pts with CTFI >180 d). The applicant states that ZEPZELCA™ was shown to be effective and well-tolerated in the platinum-sensitive relapsed SCLC population especially when CTFI >180 days. From these results, the authors concluded that ZEPZELCA™ may represent a valuable alternative to platinum rechallenge.[912] [913] The applicant also referenced Arrieta et. al., stating that ZEPZELCA™ data outperformed less established treatment schemes including platinum rechallenge.[914] The applicant stated that the July 7, 2020 NCCN Clinical Practice Guidelines in Oncology indicate that lurbinectedin is identified as a Preferred Regimen in relapse ≤6 months and a Recommended Regimen in relapse >6 months.[915] The applicant referred to the authors' conclusion in Genestreti et. al., stating that the outcome for second line chemotherapy for SCLC is poor and that rechallenge platinum/etoposide is a reasonable option with potentially better outcomes than standard chemotherapy.[916]

Finally, the applicant referred to Monnet, et. al., stating that patients treated with combination therapy, carboplatin and etoposide, achieved a median OS of 7.4 months and ORR of 49%.[917]

After review of the information provided by the applicant, we have the following concerns. The evidence submitted by the applicant in support of ZEPZELCA™'s improvement in overall response and survival rates is based on one single-arm, open label, phase II basket study (Study B–005 (NCT01454972)) and several smaller subsetted analyses that were based on the basket study, and we note that without a direct comparison arm it may be more difficult to draw definitive conclusions.[918] [919] [920] [921] We note the following differences between the historical control patients and patients treated with ZEPZELCA™ in these studies, which may confound the comparisons: First, patients with central nervous system involvement (brain metastases) were excluded from ZEPZELCA™ treatment, and we note that Arrieta, et. al., noted that this criterion is of particular interest when translating results to the clinical setting, since patients with SCLC are known to be prone to develop brain metastases, and up to 50% do so throughout the disease course.[922] Second, patients treated with ZEPZELCA™ had access to immunotherapy during first line treatment, which may support patients' immune systems in fighting cancer. Third, the CTFI used in the single arm basket trial differs from those used in the historical controls of topotecan studies, and we note that CTFIs can impact treatment response and outcome. As, per the applicant, ZEPZELCA™ was listed as a preferred regimen by the NCCN Clinical Practice Guidelines for second-line treatment of patients with a CTFI ≤6 months and recommended for patients with a CTFI >6 months, while topotecan is only FDA approved for chemotherapy-sensitive cases, defined using a 60 day CTFI, we note that the appropriate comparator treatment for ZEPZELCA™ would differ depending on the CTFI subset. However, the historical controls relied on an overall topotecan population with CTFI >60. To the extent that this group was more heavily weighted with patients in the lower CTFI group, it is unclear whether this may partially explain the poorer outcomes of patients in the historical control groups. We also note that, while the claim of improved hematological outcomes using ZEPZELCA™ appears to be mostly supported by the female-only arm of the CORAIL study, results from the pooled sample of the basket trial still appeared to demonstrate an improvement over the topotecan arm. We believe that this may suggest that the inclusion of male patients did not alter the conclusion that patients treated with ZEPZELCA™ appeared more favorable than those treated with topotecan. We further note that bone marrow stimulating drugs were allowed in the topotecan arm of the CORAIL study so the observed adverse hematologic effects may have been the best case for that arm of the study. Finally, we note that the subsetted analyses generated from the primary basket study have small sample sizes and the authors of these studies stated that further research on larger populations is required to draw firm conclusions.[923] [924]

We invite public comments on whether ZEPZELCA™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ZEPZELCA™.

6. Proposed FY 2022 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, a medical device that is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by the FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP

[912] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[913] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19–21, 2020. Poster 1784P.

[914] Arrieta O, et al. New opportunities in a challenging disease: Lurbinectedin for relapsed small-cell lung cancer. Comment in *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045(20)30097-8.*

[915] NCCN Clinical Practice Guidelines in Oncology, Small Cell Lung Cancer. Version 4.2020, July 7, 2020. *https://nccn.org.*

[916] Genestreti G, et al. Outcomes of platinum-sensitive small-cell lung cancer patients treated with platinum/etoposide rechallenge: A multi-institutional retrospective analysis. *Clinical Lung Cancer,* Vol. 16, No. 6, e223–8.

[917] Monnet, 2 L., et. al. Carboplatin-Etoposide Versus Topotecan as Second-Line Treatment for Sensitive Relapsed Small-Cell Lung Cancer: Phase 3 Trial. Journal of Thoracic Oncology Vol. 14 No. 10S

[918] Sands J, et al. Phase 2 basket trial of lurbinectedin in small-cell lung cancer (SCLC): Analysis of efficacy by baseline characteristics. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[919] Subbiah V, et al. Phase 2 basket trial of lurbinectedin in second-line SCLC: Characteristics and outcomes in treatment responders. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[920] Subbiah V, et al. Activity of lurbinectedin in second-line SCLC patients who are candidates for platinum rechallenge IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

[921] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19–21, 2020. Poster 1784P.

[922] Arrieta O, et al. New opportunities in a challenging disease: Lurbinectedin for relapsed small-cell lung cancer. Comment in *Lancet Oncology. www.thelancet.com/oncology*, Published online March 27, 2020. *https://doi.org/10.1016/S1470-2045(20)30097-8.*

[923] Subbiah V, et al. Activity in second-line SCLC patient candidates for platinum rechallenge. ESMO (European Society for Medical Oncology) 2020 Congress; September 19–21, 2020. Poster 1784P

[924] Sands J, et al. Phase 2 basket trial of lurbinectedin in small-cell lung cancer (SCLC): Analysis of efficacy by baseline characteristics. IASLC 2020 North American Conference on Lung Cancer. Accepted for presentation October 16–17, 2020.

designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still meet the cost criterion.

We note, section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. Our regulations in § 412.87(c)(2) for breakthrough devices and § 412.87(d)(2) for certain antimicrobial products state that a medical device/product that meets the condition in paragraph (c)(1) or (d)(1) of § 412.87 will be considered new for not less than 2 years and not more than 3 years after the point at which data begin to become available reflecting the inpatient hospital code (as defined in section 1886(d)(5)(K)(iii) of the Act) assigned to the new technology (depending on when a new code is assigned and data on the new technology become available for DRG recalibration). After CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology, the medical technology will no longer be considered ''new'' under the criterion of this section.

We received 17 applications for new technology add-on payments for FY 2022 under the alternative new technology add-on payment pathway. One applicant withdrew its application prior to the issuance of this proposed rule. Of the remaining 16 applications, 13 of the technologies received a Breakthrough Device designation from FDA and three were designated as a QIDP by FDA. We did not receive any applications for technologies approved through the LPAD pathway.

In accordance with the regulations under § 412.87(e)(2), applicants for new technology add-on payments, including Breakthrough Devices, must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742), we revised the regulations at § 412.87(e) by adding a new paragraph (3) which provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2021 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in this proposed rule we are making a proposal to approve or disapprove each of these 16 applications for FY 2022 new technology add-on payments. Therefore, in this section of the preamble of this proposed rule, we provide background information on each alternative pathway application and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2022. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for a complete discussion of the alternative new technology add-on payment pathways for these technologies.

a. Alternative Pathway for Breakthrough Devices

(1) Aprevo™ Intervertebral Body Fusion Device

Carlsmed, Inc. submitted an application for new technology-add on payments for the aprevo™ Intervertebral Fusion Device (aprevo™) for FY 2022. Per the applicant, the device is an interbody fusion implant that stabilizes the lumbar spinal column and facilitates fusion during lumbar fusion procedures indicated for the treatment of spinal deformity. The applicant states that the implant device is custom made for patient-specific features, by using patient CT scans to create 3D virtual models of the deformity. The device is used during anterior lumbar interbody fusion, lateral lumbar interbody fusion, transforaminal lumbar interbody fusion, or standalone anterior lumbar interbody fusion procedures. According to the applicant, the aprevo™ device is additively manufactured and made from Titanium Alloy (Ti-6Al-4V) per ASTM F3001, and has a cavity intended for the packing of bone graft. In addition, the applicant explained that aprevo™ is used with supplemental fixation devices and bone graft packing. Per the applicant, the device was formerly known as ''Corra™.''

The aprevo™ device received FDA Breakthrough Device designation under the name ''Corra'' on July 1, 2020 for the Corra Anterior, Corra Transforaminal and Corra Lateral Lumbar Fusion System interbody device which is intended for use in anterior lumbar interbody fusion (ALIF), lateral lumbar interbody fusion (LLIF), and transforaminal lumbar interbody fusion (TLIF) under this designation. The applicant was granted FDA 510(k) clearance as a Class II medical device for the anterior lumbar interbody fusion and lateral lumbar interbody fusion indications on December 3, 2020. The applicant anticipates that the aprevo™ device will receive FDA marketing authorization by May 2021 for the additional indications of transforaminal interbody fusion and standalone anterior lumbar interbody fusion (which incorporates supplemental fixation). Since the anterior and lateral lumbar fusion indications that received marketing authorization on December 3, 2020 correspond to the indications that received Breakthrough Device designation, it appears that the newness date for these indications would be December 3, 2020. The transforaminal interbody fusion indication, which also corresponds to the indication that received Breakthrough Device designation, would have a different newness date, depending on when marketing authorization is received for that indication. We note that under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of aprevo™ for the ALIF, LLIF, and TLIF indications, and the FDA Breakthrough Device designations it received for these uses, are relevant for purposes of the new technology add-on payment application for FY 2022.

According to the applicant, there are currently no unique ICD–10–PCS codes describing the device. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a code for FY

2022 to uniquely identify the technology.

With respect to the cost criterion, the applicant provided the following analysis. The applicant used the MS–DRG grouping function within FindACode software in conjunction with the online MS–DRG v37.0 Definitions Manual to identify the appropriate MS–DRGs to which potential cases that may be eligible for treatment involving aprevo™ patient-specific interbody cages would most likely map. The applicant identified the following six relevant MS–DRGs:

MS-DRG	DESCRIPTOR
453	Combined Anterior/Posterior Spinal Fusion With Mcc
454	Combined Anterior/Posterior Spinal Fusion With Cc
455	Combined Anterior/Posterior Spinal Fusion Without Cc/Mcc
456	Spinal Fusion Except Cervical With Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions With Mcc
457	Spinal Fusion Except Cervical With Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions With Cc
458	Spinal Fusion Except Cervical With Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions Without Cc/Mcc

The applicant conducted a review of ICD–10–PCS codes for procedures in which the aprevo™ patient-specific intervertebral body fusion cases might be placed into the lumbar spine of an adult patient diagnosed with spinal curvature. For MS–DRGs 453, 454, and 455, the applicant searched the FY 2019 MedPAR dataset for cases with any of the following procedure codes:

0SG00A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG10A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0SG10AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0SG13A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG13AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG14A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG14AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG30A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG30AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG33AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG34AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

For MS–DRGs 456, 457, and 458, the applicant searched the FY 2019 MedPAR dataset for cases reporting a procedure code in Table A in combination with a primary diagnosis code in Table B or a secondary diagnosis code in Table C.

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Table A – Procedure Codes	
0RGA3A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0RGA3AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0RGA4A0	Fusion of thoracolumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0RGA4AJ	Fusion of thoracolumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG00A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG00AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG03A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG03AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG04A0	Fusion of lumbar vertebral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG04AJ	Fusion of lumbar vertebral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG10A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, open approach
0SG10AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, open approach
0SG13A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG13AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG14A0	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG14AJ	Fusion of 2 or more lumbar vertebral joints with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach
0SG30A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, open approach
0SG30AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, open approach
0SG33A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous approach
0SG33AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous approach
0SG34A0	Fusion of lumbosacral joint with interbody fusion device, anterior approach, anterior column, percutaneous endoscopic approach
0SG34AJ	Fusion of lumbosacral joint with interbody fusion device, posterior approach, anterior column, percutaneous endoscopic approach

Table B – Primary Diagnosis Codes	
M4000	Postural kyphosis, site unspecified
M4004	Postural kyphosis, thoracic region
M4005	Postural kyphosis, thoracolumbar region
M4010	Other secondary kyphosis, site unspecified
M4014	Other secondary kyphosis, thoracic region
M4015	Other secondary kyphosis, thoracolumbar region
M40204	Unspecified kyphosis, thoracic region
M40205	Unspecified kyphosis, thoracolumbar region
M40209	Unspecified kyphosis, site unspecified
M40294	Other kyphosis, thoracic region
M40295	Other kyphosis, thoracolumbar region
M40299	Other kyphosis, site unspecified
M4030	Flatback syndrome, site unspecified
M4035	Flatback syndrome, thoracolumbar region
M4036	Flatback syndrome, lumbar region
M4037	Flatback syndrome, lumbosacral region
M4040	Postural lordosis, site unspecified
M4045	Postural lordosis, thoracolumbar region
M4046	Postural lordosis, lumbar region
M4047	Postural lordosis, lumbosacral region
M4050	Lordosis, unspecified, site unspecified
M4055	Lordosis, unspecified, thoracolumbar region
M4056	Lordosis, unspecified, lumbar region
M4057	Lordosis, unspecified, lumbosacral region
M4120	Other idiopathic scoliosis, site unspecified
M4124	Other idiopathic scoliosis, thoracic region
M4125	Other idiopathic scoliosis, thoracolumbar region
M4126	Other idiopathic scoliosis, lumbar region
M4127	Other idiopathic scoliosis, lumbosacral region
M4130	Thoracogenic scoliosis, site unspecified
M4134	Thoracogenic scoliosis, thoracic region
M4135	Thoracogenic scoliosis, thoracolumbar region
M4140	Neuromuscular scoliosis, site unspecified
M4144	Neuromuscular scoliosis, thoracic region
M4145	Neuromuscular scoliosis, thoracolumbar region
M4146	Neuromuscular scoliosis, lumbar region
M4147	Neuromuscular scoliosis, lumbosacral region
M4150	Other secondary scoliosis, site unspecified
M4154	Other secondary scoliosis, thoracic region
M4155	Other secondary scoliosis, thoracolumbar region
M4156	Other secondary scoliosis, lumbar region
M4157	Other secondary scoliosis, lumbosacral region
M4180	Other forms of scoliosis, site unspecified
M4184	Other forms of scoliosis, thoracic region
M4185	Other forms of scoliosis, thoracolumbar region
M4186	Other forms of scoliosis, lumbar region
M4187	Other forms of scoliosis, lumbosacral region
M419	Scoliosis, unspecified
M438X4	Other specified deforming dorsopathies, thoracic region
M438X5	Other specified deforming dorsopathies, thoracolumbar region
M438X6	Other specified deforming dorsopathies, lumbar region
M438X7	Other specified deforming dorsopathies, lumbosacral region
M438X8	Other specified deforming dorsopathies, sacral and sacrococcygeal region
M438X9	Other specified deforming dorsopathies, site unspecified
M439	Deforming dorsopathy, unspecified
M4850XA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
M4854XA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
M4855XA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M4856XA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M4857XA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M4858XA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
M8008XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M8088XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M8458XA	Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture
M8468XA	Pathological fracture in other disease, other site, initial encounter for fracture

Table B – Primary Diagnosis Codes	
M962	Postradiation kyphosis
M963	Postlaminectomy kyphosis
M964	Postsurgical lordosis
M965	Postradiation scoliosis
Q675	Congenital deformity of spine
Q763	Congenital scoliosis due to congenital bony malformation
Q76425	Congenital lordosis, thoracolumbar region
Q76426	Congenital lordosis, lumbar region
Q76427	Congenital lordosis, lumbosacral region
Q76428	Congenital lordosis, sacral and sacrococcygeal region
Q76429	Congenital lordosis, unspecified region

Table C – Secondary Diagnosis Codes	
M4010	Other secondary kyphosis, site unspecified
M4014	Other secondary kyphosis, thoracic region
M4015	Other secondary kyphosis, thoracolumbar region
M4140	Neuromuscular scoliosis, site unspecified
M4144	Neuromuscular scoliosis, thoracic region
M4145	Neuromuscular scoliosis, thoracolumbar region
M4146	Neuromuscular scoliosis, lumbar region
M4147	Neuromuscular scoliosis, lumbosacral region
M4150	Other secondary scoliosis, site unspecified
M4154	Other secondary scoliosis, thoracic region
M4155	Other secondary scoliosis, thoracolumbar region
M4156	Other secondary scoliosis, lumbar region
M4157	Other secondary scoliosis, lumbosacral region
M438X9	Other specified deforming dorsopathies, site unspecified

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The applicant identified 45,331 cases across all six MS–DRGs. The applicant first removed charges to account for the two types of prior technology devices that the applicant asserted are most likely to be replaced by aprevo™ Intervertebral Body Fusion Device. Specifically, the applicant calculated an average cost for the top five selling devices in each category of prior technology, which include standalone ALIF and LLIF lateral expandable cages.[925] The applicant then multiplied the cost of the technology being replaced by three, which, per the applicant, is the number of lumbar cages implanted for the correction of spinal curvature, to arrive at an estimated hospital cost per case.[926] The applicant converted costs to charges by weighting the operating cost-to-charge ratios for each of the 3,315 hospitals in the FY 2021 IPPS/LTCH final rule and correction notice impact file by each hospital's share of the 9,235,824 submitted bills to obtain a national average CCR of 0.2546, of which the inverse is a national-average hospital markup of 393 percent. The applicant then standardized the charges and applied an inflation factor of 13.1 percent, which, per the applicant, is the outlier charge inflation factor used in the FY 2021 IPPS/LTCH final rule (85 FR 59038), to update the charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure.

The applicant then added charges for the new technology by multiplying the estimated average cost for the aprevo™ Intervertebral Body Fusion Device by three devices per case and converting the cost to charges using the 393 percent hospital charge markup.

The applicant calculated a final inflated case-weighted average standardized charge per case of $247,648 and an average case-weighted threshold of $157,600. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the aprevo™ Intervertebral Body Fusion meets the cost criterion and therefore are proposing to approve the aprevo™ Intervertebral Body Fusion device for the indications of ALIF and LLIF, and for the indication of TLIF, subject to the technology receiving FDA marketing authorization for that indication by July 1, 2021, as these indications correspond to the Breakthrough Device designation, for new technology add-on payments for FY 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the aprevo™ Intervertebral Body Fusion is $31,500, or an estimated average cost of $10,500 per device multiplied by three, which, according to the applicant, is the average number of devices used per procedure. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the aprevo™ Intervertebral Body Fusion Device would be $20,475 for FY 2022

[925] Orthopedic Network News. ''2019 Spinal Surgery update.'' Volume 30, No. 4. October 2019.
[926] Ibid.

(that is 65 percent of the average cost of the technology).

We are inviting public comments on whether the aprevo™ Intervertebral Body Fusion Device meets the cost criterion and our proposal to approve new technology add-on payments for aprevo™ Intervertebral Body Fusion Device for FY 2022 for ALIF and LLIF, and for TLIF, subject to the technology receiving marketing authorization for that indication by July 1, 2021.

(2) aScope™ Duodeno

Ambu, Inc. submitted an application for new technology add on payments for the aScope™ Duodeno for FY 2022. The device is a sterile, single-use endoscope for endoscopy and endoscopic surgery indicated for treatment of the upper gastrointestinal (GI) tract. Per the applicant, the device includes a flexible insertion tube with a bendable tip equipped with lighting and camera. According to the applicant, the aScope™ Duodeno is inserted into the mouth of the patient and steered via the esophagus and stomach to the duodenum. The applicant states that single-use scopes eliminate the risk of patient-to-patient transmission of infection related to reprocessing. The applicant also states the device is designed to be used with aBox Duodeno, which is a video processor that outputs video imaging for observation and recording. Per the applicant, the device may also be used with existing external video monitors for image display as well as other endoscopic accessories and equipment.

The aScope™ Duodeno (formerly aScope 1 Duo) was designated as a Breakthrough Device, indicated for use with the aScope Base (now aBox Duodeno), endo-therapy accessories (for example, biopsy forceps) and other ancillary equipment (for example, video monitor) for endoscopy and endoscopic surgery within the duodenum, and received FDA 510(k) clearance as a Class II medical device on July 17, 2020 for the same indication. Per the applicant, the device was available on the market immediately after FDA clearance. According to the applicant, there are currently no unique ICD–10–PCS codes describing the device. The applicant stated that the applicant for EXALT™ Model D, another technology discussed in this section, submitted a request to the ICD–10 Coordination and Maintenance Committee for FY 2022 for a unique code to identify use of single-use duodenoscopes. The applicant further stated that since this code would describe and identify use of aScope, they did not submit a request for approval of a code to uniquely identify the technology.

To demonstrate that the technology meets the cost criterion, the applicant searched the FY 2019 MedPAR Limited Data Set (LDS) for cases reporting one of the following ICD–10–PCS codes commonly used to report endoscopic retrograde cholangiopancreatography (ERCP) and use of duodenoscopes:

0FD48ZX	Extraction of gallbladder, via natural or artificial opening endoscopic, diagnostic
0FD58ZX	Extraction of right hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FD68ZX	Extraction of left hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FD78ZX	Extraction of common hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FD88ZX	Extraction of cystic duct, via natural or artificial opening endoscopic, diagnostic
0FD98ZX	Extraction of common bile duct, via natural or artificial opening endoscopic, diagnostic
0FDC8ZX	Extraction of ampulla of vater, via natural or artificial opening endoscopic, diagnostic
0FDD8ZX	Extraction of pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FDF8ZX	Extraction of accessory pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FJ48ZZ	Inspection of gallbladder, via natural or artificial opening endoscopic
0FJB8ZZ	Inspection of hepatobiliary duct, via natural or artificial opening endoscopic
0FJD8ZZ	Inspection of pancreatic duct, via natural or artificial opening endoscopic
0FB48ZX	Excision of gallbladder, via natural or artificial opening endoscopic, diagnostic
0FB58ZX	Excision of right hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FB68ZX	Excision of left hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FB78ZX	Excision of common hepatic duct, via natural or artificial opening endoscopic, diagnostic
0FB88ZX	Excision of cystic duct, via natural or artificial opening endoscopic, diagnostic
0FB98ZX	Excision of common bile duct, via natural or artificial opening endoscopic, diagnostic
0FBC8ZX	Excision of ampulla of vater, via natural or artificial opening endoscopic, diagnostic
0FBD8ZX	Excision of pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FBF8ZX	Excision of accessory pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FN98ZZ	Release common bile duct, via natural or artificial opening endoscopic
0FNC8ZZ	Release ampulla of vater, via natural or artificial opening endoscopic
0FND8ZZ	Release pancreatic duct, via natural or artificial opening endoscopic
0FNF8ZZ	Release accessory pancreatic duct, via natural or artificial opening endoscopic
4A0C8BZ	Measurement of biliary pressure, via natural or artificial opening endoscopic
0FF78ZZ	Fragmentation in common hepatic duct, via natural or artificial opening endoscopic
0FF98ZZ	Fragmentation in common bile duct, via natural or artificial opening endoscopic

The applicant excluded MS–DRGs that had fewer than 100 cases from the analysis. The applicant did not say how many cases it excluded based on this criterion.

In total, the applicant identified 54,848 cases across 40 unique MS–DRGs. The applicant then removed charges for prior technology by dividing the per use cost for reusable duodenoscopes and related components [927] by the hospital-specific cost-to-charge ratio from the FY 2021

[927] Derived from Travis, et al. minus the 20 percent overhead cost.

IPPS/LTCH Proposed Rule Impact File at the claims level and averaging the resulting estimated charges by MS–DRG. The applicant then standardized the charges and applied an inflation factor of 13.2 percent, or the 2-year inflation factor used to update the outlier threshold in the FY 2021 IPPS/LTCH final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. The applicant added charges for the aScope™ Duodeno and related components by dividing the cost per use by the national cost-to-charge ratio of 0.2970 for Supplies and Equipment (85 FR 58601).

The applicant calculated a final inflated average case-weighted standardized charge per case of $89,945 and an average case-weighted threshold of $64,894. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the aScope™ Duodeno meets the cost criterion; and therefore, we are proposing to approve the aScope™ Duodeno for new technology add-on payments for FY 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the aScope™ Duodeno is $2,184.27. However, the applicant noted in its application that this cost is broken down into three components, including the disposable sleeve, the aBox Duodeno (a video processor and light source), and other endoscopic accessories and equipment. We believe it is appropriate to only consider the cost of the disposable sleeve as the cost of the technology, as the other two components, which include the aBox Duodeno and an external monitor that, per the applicant, do not incur new costs per use, would thus be paid for under the IPPS for capital-related costs. As noted previously, because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add on payments under the IPPS for capital-related costs. Thus, we believe the operating cost of the aScope™ Duodeno is $1,995.

Based on the information available at the time of this proposed rule, it appears that both aScope™ Duodeno and EXALT™ Model D will be identified by the same ICD–10–PCS code and share the same indication for endoscopy and endoscopic surgery within the duodenum. As we are unable to separately identify these cases to apply two separate payment amounts for these technologies, we are proposing to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amount for both technologies. To compute the weighted average cost, we summed the total number of projected cases for each of the applicants, which equaled 12,064 (3,750 plus 8,314). Then we divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. We multiplied the cost per case for the manufacturer specific technology by the case-weighted percentage (0.31 * $1,995 = $620.13 for aScope™ Duodeno and 0.69 * $2,930 = $2,019.23 for EXALT™ Model D). This resulted in a case-weighted average cost of $2,639.36 for both technologies. We are inviting public comments on this proposed case-weighted average, as well as any alternative approaches for determining and applying the new technology add-on payment amount for cases involving these technologies, for FY 2022.

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of aScope™ Duodeno or EXALT™ Model D would be $1,715.59 for FY 2022 (that is, 65 percent of the case-weighted average cost of both technologies).

We are inviting public comments on whether aScope™ Duodeno meets the cost criterion and our proposal to approve new technology add-on payments for aScope™ Duodeno for FY 2022. We are further inviting public comments on the calculation of the maximum new technology add-on payment amount for the aScope™ Duodeno.

(3) Caption Guidance™

Caption Health, Inc. submitted an application for new technology-add on payments for Caption Guidance™ for FY 2022. Per the applicant, Caption Guidance™ is an artificial intelligence (AI) guided medical imaging acquisition software system indicated for the acquisition of cardiac ultrasound images. The applicant explained that the system provides real-time guidance during transthoracic echocardiography (2D–TTE) to assist in obtaining anatomically correct and optimized images that represent standard 2D echocardiographic diagnostic views and orientations. The applicant also states that the technology is classified by FDA as software as a medical device (SaMD), so in order to use the software, the Caption Guidance™ system must be installed on a compatible third-party ultrasound system.

Caption Guidance™ is designated as a Breakthrough Device, indicated to assist medical professionals in the acquisition of cardiac ultrasound images, and received FDA De Novo approval on February 7, 2020 for the same indication. The applicant stated that an updated version of the system subsequently received 510(k) clearance under 510(k) number K200755 on April 16, 2020 on an expedited basis due to COVID–19. Per the applicant, an interim version of the software became available on March 17, 2020, though not sold, on an emergency basis to assist sites in responding to the COVID–19 pandemic. According to the applicant, the first version of the technology was released commercially on September 15, 2020 with a first date of sale of September 29, 2020. Therefore, we believe that the newness date for this technology is the date on which Caption Guidance™ became available on the market, September 15, 2020. The item is a Class II medical device assigned to product code QJU with descriptor Image Acquisition And/Or Optimization Guided By Artificial Intelligence. According to the applicant, there are currently no unique ICD–10–PCS codes describing the device. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for a new code to uniquely identify the technology.

With respect to the cost criterion, the applicant searched the CY 2019 Limited Data Set (LDS)—Carrier Standard Analytic File (SAF), 5 percent sample, for beneficiaries receiving limited echocardiography, as described by Current Procedural Terminology (CPT®) code 93308 (Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, follow-up or limited study) with a place of service code 21 (inpatient hospital) or 23

(emergency department) and the associated inpatient stays. Per the applicant, limited echocardiography, the procedure most likely to include Caption Guidance, is not reliably reported in the inpatient setting. As a result, the applicant used a multi-step approach where corresponding inpatient stays were identified in the CY 2019 LDS—Inpatient SAF for the beneficiaries identified in the Carrier SAF. Inpatient stays were identified by matching on the unique beneficiary ID and by matching the carrier claim date of service against the inpatient admission and discharge dates. The applicant counted an inpatient stay if the date of service for CPT code 93308 occurred on or after the inpatient admission date (or during the three days preceding the date of admission), but was also on or before the discharge date of the hospital stay. The applicant eliminated non-inpatient claims and claims with a payment amount less than or equal to zero, as well as claims from hospitals that are not used in the ratesetting process.

The applicant summarized the remaining claims by MS–DRG, and by principal diagnosis and MS–DRG. The applicant cross-walked the MS–DRG codes to FY 2021 MS–DRG definitions using the MS–DRG grouper for FY 2021 and identified a list of 461 unique MS–DRGs to which cases representing patients who may be eligible for use of Caption Guidance™ mapped. The applicant also utilized data from current Caption Guidance™ customers to obtain a list of principal diagnoses associated with each MS–DRG. The applicant noted that, because this analysis began with the CY 2019 LDS Carrier SAF, 5 percent sample, the inpatient claims captured underrepresent the total number of inpatient stays in which CPT code 93308 is expected to be performed. The applicant applied the unique MS–DRG and principal diagnosis combinations to all inpatient claims in the CY 2018 and CY 2019 LDS SAF with a discharge date in FY 2019. The applicant then removed any claims where there were no billed charges in revenue centers 0480 (Cardiology-General) and 0483 (Cardiology-Echocardiology). The applicant explained that MS–DRG and principal diagnosis alone are unlikely to be a good proxy for performance of CPT code 93308. The applicant noted that there are charges to revenue centers 0480 and 0483 among nearly 100 percent of cases identified, and that no other revenue centers were billed at such high frequency. The applicant explained that it did not use the FY 2021 MedPAR LDS for this reason, as the dataset does not report charges by revenue center.

The applicant identified 1,932,386 cases mapping to 461 MS–DRGs. Then the applicant standardized the charges and applied the 2-year charge inflation factor used to adjust the outlier threshold determination, which the applicant stated was 10.22 percent. We note that the applicant appears to have used an inflation factor lower than the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure. The applicant did not remove charges for prior technology as the applicant maintained that no existing technology is comparable to Caption Guidance™.

The applicant then added charges for the new technology. The applicant calculated the technology's cost per case in a multi-step process. First, the applicant multiplied the cost of Caption Guidance™ by the number of devices under the CCN of each subscribing provider to obtain a provider-specific total device cost. Next, for each subscribing provider, the applicant identified Medicare inpatient cases that would be eligible for Caption Guidance™ using the criteria and methodology described previously. The applicant then multiplied the number of inpatient cases by 15 percent, which per the applicant is consistent with published evidence that the percent of limited echocardiography cases ranged from 12 to 15 percent of all inpatient echocardiography services.[928] The applicant then added the number of Medicare hospital outpatient cases for CPT code 93308 for each subscribing provider to the estimated inpatient limited echocardiography utilization to estimate total Medicare limited echocardiography by provider. The applicant divided the total Medicare inpatient and outpatient cases receiving limited echocardiogram by an average Medicare share of 63 percent, which the applicant estimated by analyzing discharges reporting three ICD–10–PCS codes: B244ZZZ (Ultrasonography of right heart), B245ZZZ (Ultrasonography of left heart), and B246ZZZ (Ultrasonography of right and left heart) from HCUPnet's Nationwide Inpatient Sample, 2017, to obtain the total limited echocardiography cases. The applicant then divided the total device cost by the total limited echocardiography cases to obtain a provider-specific cost per case, which it then averaged across all subscriber hospitals. Finally, the applicant converted the cost per case to charges per case by dividing the cost per case by the national average cost-to-charge ratio for the cardiology cost center of 0.094 (85 FR 58601).

The applicant calculated a final inflated case-weighted average standardized charge per case of $113,435 and an average case-weighted threshold of $69,197. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that, using the cost per case provided by the applicant, the Caption Guidance™ system would meet the cost criterion and therefore are proposing to approve the Caption Guidance™ system for new technology add-on payments for FY 2022. However, as we note later in this section, because the cost per case can vary based on utilization of the technology, we would like further information on whether the Caption Guidance™ system would still meet the cost criterion if, for instance, an increase in utilization resulted in a cost per case that is lower than the figure the applicant provided.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the Caption Guidance™ system is $2,874. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Caption Guidance™ system would be $1,868.10 for FY 2022 (that is 65 percent of the average cost of the technology). However, we refer the reader to our discussion and request for comments regarding our concerns with respect to determining a cost per case for a technology that utilizes a subscription for its cost, and note that we may consider finalizing a different add-on payment amount after consideration of comments received.

The applicant appears to have used a single list price of Caption Guidance™ per hospital with a cost per patient that can vary based on the volume of cases. We are interested in information about

[928] Ward RP, Lee L, Ward TJ, Lang RM. Utilization and Appropriateness of Transthoracic Echocardiography in Response to the COVID–19 Pandemic. *J Am Soc Echocardiogr.* 2020 June;33(6):690–691. doi: 10.1016/j.echo.2020.04.006. Epub 2020 April 10.

whether the cost per patient varies based on the utilization of the technology by the hospitals. The cost per patient could be skewed by the small number of hospitals utilizing the technology and their low case volumes. It is possible, if hospitals with large patient populations adopt Caption Guidance™, the cost per patient would be significantly lower.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58628), in a similar instance, we stated our understanding that there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We continue to welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so, whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We invite public comments on whether the Caption Guidance™ system meets the cost criterion and our proposal to approve new technology add-on payments for Caption Guidance™ system for FY 2022, including on whether the newness period for this technology would begin on September 15, 2020.

(4) CERAMENT® G

BONESUPPORT Inc. submitted an application for new technology-add on payments for CERAMENT® G for FY 2022. Per the applicant, CERAMENT® G is an injectable bone-void filler made of calcium sulfate, hydroxyapatite, and gentamicin sulfate indicated for the surgical treatment of osteomyelitis. Per the applicant, this bone graft substitute fills gaps resulting from debridement of infected bone and prevents colonization of sensitive bacteria, promoting bone healing in two ways. The applicant stated that the primary mode of action is for CERAMENT® G to act as a resorbable ceramic bone-void filler intended to fill gaps and voids in the skeleton system created when infected bone is debrided. The applicant also stated that the secondary mode of action is to prevent the colonization of gentamicin-sensitive microorganisms in order to protect bone healing. Per the applicant, CERAMENT® G may eliminate the need to harvest autologous bone, avoiding pain and infection at the donor site.

CERAMENT® G is designated as a Breakthrough Device for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis. It has not yet received FDA 510(k) clearance. According to the applicant, there are no available codes that adequately describe the product CERAMENT® G. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a code to uniquely identify the technology.

With respect to the cost criterion, the applicant used the MS–DRG grouping function within FindACode software in conjunction with the online MS–DRG v37.0 Definitions Manual to identify the appropriate MS–DRGs to which potential cases that may be eligible for treatment with CERAMENT® G would most likely map. The applicant identified the following seven relevant MS–DRGs:

MS-DRG	DESCRIPTOR
464	Wound debridement and skin graft except hand for musculoskeletal system and connective tissue disorders with CC
493	Lower extremity and humerus procedures except hip, foot and femur with CC
496	Local excision and removal of internal fixation devices except hip and femur with CC
498	Local excision and removal internal fixation devices of hip and femur with CC/MCC
504	Foot procedures with CC
511	Shoulder, elbow or forearm procedures, except major joint procedures with CC
516	Other musculoskeletal system and connective tissue O.R. procedures with CC

The applicant conducted a review of ICD–10–PCS codes for procedures that would use CERAMENT® G. For each MS–DRG, the applicant searched for cases reporting a diagnosis code from the Osteomyelitis category in combination with one of the procedure codes listed in the table that follows.

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MS-DRG 464	0PBK0ZZ	Excision of right ulna, open approach
	0PBL0ZZ	Excision of left ulna, open approach
	0PDK0ZZ	Extraction of right ulna, open approach
	0PDL0ZZ	Extraction of left ulna, open approach
MS-DRG 493	0PBC0ZZ	Excision of right humeral head, open approach
	0PBD0ZZ	Excision of left humeral head, open approach
	0PBF0ZZ	Excision of right humeral shaft, open approach
	0PBG0ZZ	Excision of left humeral shaft, open approach
	0PDF0ZZ	Extraction of right humeral shaft, open approach
	0PDG0ZZ	Extraction of left humeral shaft, open approach
	0PTC0ZZ	Resection of right humeral head, open approach
	0PTD0ZZ	Resection of left humeral head, open approach
	0PTF0ZZ	Resection of right humeral shaft, open approach
	0PDG0ZZ	Extraction of left humeral shaft, open approach
	0PCC0ZZ	Extirpation of matter from right humeral head, open approach
	0PCF0ZZ	Extirpation of matter from right humeral shaft, open approach
	0PCG0ZZ	Extirpation of matter from left humeral shaft, open approach
	0PDC0ZZ	Extraction of right humeral head, open approach
	0PDD0ZZ	Extraction of left humeral head, open approach
	0PDF0ZZ	Extraction of right humeral shaft, open approach
	0PDG0ZZ	Extraction of left humeral shaft, open approach
	0QBG0Z Z	Excision of right tibia, open approach
	0QBH0Z Z	Excision of left tibia, open approach
	0QBJ0ZZ	Excision of right fibula, open approach
	0QBK0Z Z	Excision of left fibula, open approach
	0QCG0Z Z	Extirpation of matter from right tibia, open approach
	0QCH0Z Z	Extirpation of matter from left tibia, open approach
	0QCJ0ZZ	Extirpation of matter from right fibula, open approach

	0QCK0ZZ	Extirpation of matter from left fibula, open approach
	0QDG0ZZ	Extraction of right tibia, open approach
	0QDH0ZZ	Extraction of left tibia, open approach
	0QDJ0ZZ	Extraction of right fibula, open approach
	0QDK0ZZ	Extraction of left fibula, open approach
	0PCD0ZZ	Extirpation of matter from left humeral head, open approach
MS-DRG 496	0MR507Z	Replace of right wrist bursa and ligament with autologous tissue substitute, open approach
	0P9H0ZZ	Drainage of right radius, open approach
	0P9J0ZZ	Drainage of left radius, open approach
	0P9K0ZZ	Drainage of right ulna, open approach
	0P9L0ZZ	Drainage of left ulna, open approach
	0PCH0ZZ	Extirpation of matter from right radius, open approach
	0PCJ0ZZ	Extirpation of matter from left radius, open approach
	0PCK0ZZ	Extirpation of matter from right ulna, open approach
	0PCL0ZZ	Extirpation of matter from left ulna, open approach
	0PCM0ZZ	Extirpation of matter from right carpal, open approach
	0PCN0ZZ	Extirpation of matter from left carpal, open approach
	0Q920ZZ	Drainage of right pelvic bone, open approach
	0Q9230Z	Drainage of right pelvic bone with drainage device, percutaneous approach
	0Q9240Z	Drainage of right pelvic bone with drainage device, percutaneous endoscopic approach
	0Q950ZZ	Drainage of left acetabulum, open approach
	0QC20ZZ	Extirpation of matter from right pelvic bone, open approach
	0QC30ZZ	Extirpation of matter from left pelvic bone, open approach
	0QC40ZZ	Extirpation of matter from right acetabulum, open approach
	0QC50ZZ	Extirpation of matter from left acetabulum, open approach
	0P9C0ZZ	Drainage of right humeral head, open approach
	0P9D0ZZ	Drainage of left humeral head, open approach
	0P9F0ZZ	Drainage of right humeral shaft, open approach
	0P9G0ZZ	Drainage of left humeral shaft, open approach
	0Q9G0ZZ	Drainage of right tibia, open approach
	0Q9H0ZZ	Drainage of left tibia, open approach
	0Q9J0ZZ	Drainage of right fibula, open approach
	0Q9K0ZZ	Drainage of left fibula, open approach
	0QCG0ZZ	Extirpation of matter from right tibia, open approach
	0QCJ0ZZ	Extirpation of matter from right fibula, open approach
	0S9F0ZZ	Drainage of right ankle joint, open approach
	0S9G0ZZ	Drainage of left ankle joint, open approach
	0P9700Z	Drainage of right glenoid cavity with drainage device, open approach
	0P9800Z	Drainage of left glenoid cavity with drainage device, open approach
	0P9C00Z	Drainage of right humeral head with drainage device, open approach
	0P9D00Z	Drainage of left humeral head with drainage device, open approach
	0P5H0ZZ	Destruction of right radius, open approach
	0P5J0ZZ	Destruction of left radius, open approach
	0PBH0ZZ	Excision of right radius, open approach
	0PBJ0ZZ	Excision of left radius, open approach
MS-DRG 498	0Q960ZZ	Drainage of right upper femur, open approach
	0Q970ZZ	Drainage of left upper femur, open approach
	0Q980ZZ	Drainage of right femoral shaft, open approach
	0Q990ZZ	Drainage of left femoral shaft, open approach
	0Q9B0ZZ	Drainage of right lower femur, open approach
	0Q9C0ZZ	Drainage of left lower femur, open approach
	0Q9D0ZZ	Drainage of right patella, open approach

	0Q9F0ZZ	Drainage of left patella, open approach
	0QB80ZZ	Excision of right femoral shaft, open approach
	0QB90ZZ	Excision of left femoral shaft, open approach
	0QBB0ZZ	Excision of right lower femur, open approach
	0QBC0ZZ	Excision of left lower femur, open approach
	0QBG0ZZ	Excision of right tibia, open approach
	0QBH0ZZ	Excision of left tibia, open approach
	0QBJ0ZZ	Excision of right fibula, open approach
	0QBK0ZZ	Excision of left fibula, open approach
	0QB60ZZ	Excision of right upper femur, open approach
	0QD80ZZ	Extraction of right femoral shaft, open approach
	0QD90ZZ	Extraction of left femoral shaft, open approach
	0QDB0ZZ	Extraction of right lower femur, open approach
	0QDC0ZZ	Extraction of left lower femur, open approach
	0QDG0ZZ	Extraction of right tibia, open approach
	0QDH0ZZ	Extraction of left tibia, open approach
	0QDJ0ZZ	Extraction of right fibula, open approach
	0QDK0ZZ	Extraction of left fibula, open approach
	0Q560ZZ	Destruction of right upper femur, open approach
	0Q570ZZ	Destruction of left upper femur, open approach
	0QB60ZZ	Excision of right upper femur, open approach
	0QB70ZZ	Excision of left upper femur, open approach
	0QC70ZZ	Extirpation of matter from left upper femur, open approach
	0QD20ZZ	Extraction of right pelvic bone, open approach
	0QD30ZZ	Extraction of left pelvic bone, open approach
	0QD60ZZ	Extraction of right upper femur, open approach
	0QD70ZZ	Extraction of left upper femur, open approach
	0QC60ZZ	Extirpation of matter from right upper femur, open approach
	0QT60ZZ	Resection of right upper femur, open approach
	0QT70ZZ	Resection of left upper femur, open approach
MS-DRG 504	0QBM0ZZ	Excision of left tarsal, open approach
	0QDL0ZZ	Extraction of right tarsal, open approach
	0QDM0ZZ	Extraction of left tarsal, open approach
	0Q9N0ZZ	Drainage of right metatarsal, open approach
	0Q9P0ZZ	Drainage of left metatarsal, open approach
	0QBP0ZZ	Excision of left metatarsal, open approach
	0QDN0ZZ	Extraction of right metatarsal, open approach
	0QDP0ZZ	Extraction of left metatarsal, open approach
MS-DRG 511	0P5K0ZZ	Destruction of right ulna, open approach
	0P5L0ZZ	Destruction of left ulna, open approach
	0PBK0ZZ	Excision of right ulna, open approach
	0PBL0ZZ	Excision of left ulna, open approach
	0PDK0ZZ	Extraction of right ulna, open approach
	0PDL0ZZ	Extraction of left ulna, open approach
	0PBH0ZZ	Excision of right radius, open approach
	0PBJ0ZZ	Excision of left radius, open approach
	0PDH0ZZ	Extraction of right radius, open approach
	0PDJ0ZZ	Extraction of left radius, open approach
	0PCH0ZZ	Extirpation of matter from right radius, open approach

	0PCJ0ZZ	Extirpation of matter from left radius, open approach
	0PCK0ZZ	Extirpation of matter from right ulna, open approach
	0PCL0ZZ	Extirpation of matter from left ulna, open approach
MS-DRG 516	0PC90ZZ	Extirpation of matter from right clavicle, open approach
	0PCB0ZZ	Extirpation of matter from left clavicle, open approach
	0PD90ZZ	Extraction of right clavicle, open approach
	0PDB0ZZ	Extraction of left clavicle, open approach
	0PB90ZZ	Excision of right clavicle, open approach
	0PBB0ZZ	Excision of left clavicle, open approach
	0PC50ZZ	Extirpation of matter from right scapula, open approach
	0PC60ZZ	Extirpation of matter from left scapula, open approach
	0PD50ZZ	Extraction of right scapula, open approach
	0PD60ZZ	Extraction of left scapula, open approach
	0PB50ZZ	Excision of right scapula, open approach
	0PB60ZZ	Excision of left scapula, open approach
	0PB73ZZ	Excision of right glenoid cavity, percutaneous approach
	0PB74ZZ	Excision of right glenoid cavity, percutaneous endoscopic approach
	0PB83ZZ	Excision of left glenoid cavity, percutaneous approach
	0PB84ZZ	Excision of left glenoid cavity, percutaneous endoscopic approach
	0QBQ0ZZ	Excision of right toe phalanx, open approach
	0QBR0ZZ	Excision of left toe phalanx, open approach
	0QDQ0ZZ	Extraction of right toe phalanx, open approach
	0QDR0ZZ	Extraction of left toe phalanx, open approach

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The applicant identified 7,994 cases across the seven MS–DRGs. The applicant then removed charges for prior technology that may be replaced by CERAMENT® G. The applicant conducted a market analysis that identified 3 types of prior technology devices: Poly (methyl methacrylate) (PMMA) manually mixed with antibiotics, PMMA pre-loaded with antibiotics, and calcium sulfate (CaS) mixed with antibiotics. The applicant researched the average sales price (ASP) for major competitors for 5cc and 10cc of each device type and calculated a weighted average cost of $444 per 5cc and $727 per 10 cc.[929] Then the applicant converted costs to charges by weighting the operating cost-to-charge ratios for 3,315 hospitals in the FY 2021 IPPS/LTCH PPS final rule and correction notice impact file by each hospital's share of the 9,235,824 submitted bills to obtain a national average CCR of 0.2546, of which the inverse is a national-average hospital markup of 393 percent. The applicant then standardized the charges and applied an inflation factor of 13.1 percent, or the 2-year inflation factor used to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure. The applicant added charges for the new technology by multiplying the estimated average cost for 5cc and 10cc of CERAMENT® G by the 393 percent hospital charge markup.

The applicant calculated a final inflated case-weighted average standardized charge per case of $107,671 and an average case-weighted threshold of $76,791. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that CERAMENT® G meets the cost criterion; and therefore, subject to the technology receiving FDA marketing authorization for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis by July 1, 2021, we are proposing to approve CERAMENT® G for new technology add-on payments for FY 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of CERAMENT® G is $6,020 per procedure. Per the applicant, the amount of CERAMENT® G used per patient depends on the location and size of the bone void. The applicant expects that a typical patient will require 5–10cc per procedure, with large and more complex cases requiring higher volumes. The applicant estimated that 70 percent of patients will receive 5cc and 30 percent of patients will receive 10 cc of CERAMENT® G, resulting in a weighted average cost of $6,020 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the product CERAMENT® G would be $3,913 for FY 2022 (that is 65 percent of the average cost of the technology).

[929] The applicant's analysis was informed by 2019 and 2020 data for its competitors from three sources: an iData Market Research 2019 Sku Data Report, Global Data US Hospital Bone Grafts and Substitutes Q3 2019 Report, and feedback from sales representatives in the field.

We are inviting public comments on whether CERAMENT® G meets the cost criterion and our proposal to approve new technology add-on payments for CERAMENT® G for FY 2022, subject to CERAMENT® G receiving FDA marketing authorization for use as a bone-void filler as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis by July 1, 2021.

(5) EXALT™ Model D Single-Use Duodenoscope

Boston Scientific Corporation submitted an application for new technology-add on payments for EXALT™ Model D Single-Use Duodenoscope (EXALT™) for FY 2022. Per the applicant, EXALT™ is a single-use, flexible duodenoscope indicated for diagnostic and therapeutic treatment of the pancreaticobiliary system during endoscopic retrograde cholangiopancreatography (ERCP) procedures. According to the applicant, the scope is most commonly used to facilitate therapeutic maneuvers such as removal of gallstones from the bile ducts, dilation of strictures in the bile or pancreatic ducts, or to relieve an obstruction by inserting a plastic or metal stent. The applicant states that EXALT™ is intended to eliminate the risk of patient-to-patient transmission of infection related to reprocessing of reusable duodenoscopes.

EXALT™ is designated as a Breakthrough Device, indicated for intended use with a Boston Scientific endoscopic video imaging system for endoscopy and endoscopic surgery within the duodenum, and received FDA 510(k) clearance as a Class II medical device on December 13, 2019 for the same indication. The applicant indicates that this device is the first FDA-cleared single-use duodenoscope in the U.S. According to the applicant, EXALT™ was available on the market immediately after FDA approval. The applicant listed 50 ICD–10–PCS codes that describe ERCP and other procedures in which EXALT™ and other duodenoscopes are used. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a code to uniquely identify the technology.

With respect to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 76 percent of identified claims, both of which are further described later in this section. To identify potential cases where EXALT™ could be utilized, the applicant searched the FY 2019 MedPAR file for the following ICD–10–PCS codes:

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0F558ZZ	Destruction of right hepatic duct, via natural or artificial opening endoscopic
0F568ZZ	Destruction of left hepatic duct, via natural or artificial opening endoscopic
0F578ZZ	Destruction of common hepatic duct, via natural or artificial opening endoscopic
0F588ZZ	Destruction of cystic duct, via natural or artificial opening endoscopic
0F598ZZ	Destruction of common bile duct, endoscopic
0F5C8ZZ	Destruction of ampulla of vater, endoscopic
0F5D8ZZ	Destruction of pancreatic duct, endoscopic
0F5F8ZZ	Destruction of accessory pancreatic duct, via natural or artificial opening endoscopic
0F758DZ	Dilation of right hepatic duct with intraluminal device, via natural or artificial opening endoscopic
0F758ZZ	Dilation of right hepatic duct , via natural or artificial opening endoscopic
0F768DZ	Dilation of left hepatic duct with intraluminal device, endoscopic
0F768ZZ	Dilation of left hepatic duct, endoscopic
0F778DZ	Dilation of common hepatic duct with intraluminal device, via natural or artificial opening endoscopic
0F778ZZ	Dilation of common hepatic duct, via natural or artificial opening endoscopic
0F788DZ	Dilation of cystic duct with intraluminal device, via natural or artificial opening endoscopic
0F788ZZ	Dilation of cystic duct, endoscopic
0F798DZ	Dilation of common bile duct with intraluminal device, endoscopic
0F798ZZ	Dilation of common bile duct, endoscopic
0F7C8DZ	Dilation of ampulla of vater with intraluminal device, endoscopic
0F7C8ZZ	Dilation of ampulla of vater, endoscopic
0F7D8DZ	Dilation of pancreatic duct with intraluminal device, via natural or artificial opening endoscopic
0F7D8ZZ	Dilation of pancreatic duct, endoscopic
0F7F8DZ	Dilation of accessory pancreatic duct with intraluminal device, endoscopic
0F7F8ZZ	Dilation of accessory pancreatic duct, endoscopic
0FB98ZX	Excision of common bile duct, endoscopic, diagnostic
0FBC8ZX	Excision of ampulla of vater, endoscopic, diagnostic
0FBD8ZX	Excision of pancreatic duct, endoscopic, diagnostic
0FBF8ZX	Excision of accessory pancreatic duct, via natural or artificial opening endoscopic, diagnostic
0FC58ZZ	Extirpation of matter from right hepatic duct, via natural or artificial opening endoscopic
0FC68ZZ	Extirpation of matter from left hepatic duct, via natural or artificial opening endoscopic
0FC78ZZ	Extirpation of matter from common hepatic duct, via natural or artificial opening endoscopic
0FC98ZZ	Extirpation of matter from common bile duct, endoscopic
0FCD8ZZ	Extirpation of matter from pancreatic duct, via natural or artificial opening endoscopic
0FCF8ZZ	Extirpation of matter from accessory pancreatic duct, via natural or artificial opening endoscopic
0FF58ZZ	Fragmentation in right hepatic duct, endoscopic
0FF68ZZ	Fragmentation in left hepatic duct, endoscopic
0FF78ZZ	Fragmentation in common hepatic duct, via natural or artificial opening endoscopic
0FF88ZZ	Fragmentation in cystic duct, via natural or artificial opening endoscopic
0FF98ZZ	Fragmentation in common bile duct, endoscopic
0FFC8ZZ	Fragmentation in ampulla of vater, endoscopic
0FFD8ZZ	Fragmentation in pancreatic duct, endoscopic
0FFF8ZZ	Fragmentation in accessory pancreatic duct, via natural or artificial opening endoscopic
0FHB8DZ	Insertion of intraluminal device into hepatobiliary duct, via natural or artificial opening endoscopic
0FHD8DZ	Insertion of intraluminal device into pancreatic duct, endoscopic
0FJB8ZZ	Inspection of hepatobiliary duct, via natural or artificial opening endoscopic
0FJD8ZZ	Inspection of pancreatic duct, endoscopic
0FPB80Z	Removal of drainage device from hepatobiliary duct, via natural or artificial opening endoscopic
0FPB8DZ	Removal of intraluminal device from hepatobiliary duct, via natural or artificial opening endoscopic
0FPD80Z	Removal of drainage device from pancreatic duct, endoscopic
0FPD8DZ	Removal of intraluminal device from pancreatic duct, endoscopic

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For the analysis using 100 percent of cases, the applicant identified a total of 59,966 cases spanning 440 MS–DRGs. The applicant then removed 100 percent of charges associated with the service Medical/Surgical Supplies and Devices for the prior technology. The applicant stated that it does not believe use of EXALT™ will replace any other medical supplies but removed 100 percent of charges associated with service category Medical/Surgical Supply Charge Amount, which included the revenue center code 027x, to be as conservative as possible. The applicant then standardized the charges and applied an inflation factor of 13.2 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges

from FY 2019 to FY 2021 (85 FR 59039). The applicant added charges for the new technology by multiplying the cost of the technology by the national CCR for implantable devices from the FY 2021 IPPS/LTCH PPS final rule. Under the analysis based on 100 percent of claims, the applicant determined an average case-weighted threshold amount of $66,588 and a final inflated case weighted average standardized charge per case of $96,079.

For the analysis using 76 percent of cases, which the applicant conducted due to these cases mapping to just 14 MS–DRGs, the applicant used the same methodology, which identified 45,530 cases across 14 MS–DRGs. The applicant determined an average case-weighted threshold amount of $63,762 and a final inflated case weighted average standardized charge per case of $84,631. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount for both analyses, the applicant asserted that the technology meets the cost criterion.

We are concerned that the applicant used the national CCR for implantable devices from the FY 2021 IPPS/LTCH PPS final rule, as a duodenoscope is not an implantable device. We note that the cost analysis for another duodenoscope that is the subject of an application for new technology add-on payments for FY 2022, the aScope™ Duodeno, used the national CCR for supplies and equipment to convert the cost of the technology to charges, and we believe that the same CCR should apply for purposes of the cost analysis for EXALT™ Model D Single-Use Duodenoscope.

We agree with the applicant that EXALT™ Model D Single-Use Duodenoscope meets the cost criterion and therefore are proposing to approve EXALT™ Model D Single-Use Duodenoscope for new technology add on payments for FY 2022.

As discussed previously, based on the information available at the time of this proposed rule, it appears that both aScope™ Duodeno and EXALT™ Model D will be identified by the same ICD–10–PCS code and share the same indication for endoscopy and endoscopic surgery within the duodenum. Thus, as we are unable to separately identify these cases to apply two separate payment amounts for these technologies, we are proposing to use a case-weighted average to calculate a single cost that would be used to determine the new technology add-on payment amount for both technologies. To compute the weighted average cost, we summed the total number of projected cases for each of the applicants, which equaled 12,064 (3,750 plus 8,314). Then we divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 31 percent for aScope™ Duodeno and 69 percent for EXALT™ Model D. We then multiplied the cost per case for the manufacturer specific technology by the case-weighted percentage (0.31 * $1,995 = $620.13 for aScope™ Duodeno and 0.69 * $2,930 = $2,019.23 for EXALT™ Model D). This resulted in a case-weighted average cost of $2,639.36 for both technologies. We are inviting public comments on this proposed case-weighted average, as well as any alternative approaches for determining and applying the new technology add-on payment amount for cases involving these technologies, for FY 2022.

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the product EXALT™ Model D Single-Use Duodenoscope or aScope™ Duodeno would be $1,715.59 for FY 2022 (that is 65 percent of the case-weighted average cost of both technologies).

We are inviting public comments on whether EXALT™ Model D Single-Use Duodenoscope meets the cost criterion and our proposal to approve new technology add-on payments for EXALT™ Model D Single-Use Duodenoscope for FY 2022. We are further inviting public comments on our calculation of the maximum new technology add-on payment amount for the EXALT™ Model D.

(6) FUJIFILM EP–7000X System

Fujifilm Corporation submitted an application for new technology-add on payments for FUJIFILM EP–7000X System for FY 2022. The FUJIFILM EP–7000X system is an endoscopic video imaging system used for endoscopic observation, diagnosis, treatment, and image recording in minimally invasive surgeries of abdominal gynecologic and thoracic areas. Per the applicant, this system allows for the visualization of hemoglobin oxygen saturation levels of blood in superficial tissue under a 2D endoscopic image, which helps physicians identify tissue that is not appropriately oxygenated and thus potentially ischemic. The applicant further explains that the technology consists of four components: Video Laparoscope EL–R740M, Processor VP–7000, Light Source BL–7000X, and Image Processing Unit EX–0.

The FUJIFILM EP–7000X system received Breakthrough Device designation for endoscopic observation, diagnosis, treatment, and image recording in patients requiring such procedures on September 17, 2020 and has not yet been granted FDA approval. According to the applicant, there are currently no unique ICD–10–PCS codes describing the system. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology.

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment with the EP–7000X System. The applicant identified claims that reported an ICD–10–PCS procedure code for gastrointestinal bypass or hernia repair, which the applicant listed in the following table:

BILLING CODE 4120–01–P

0D11476	Bypass upper esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D11479	Bypass upper esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1147A	Bypass upper esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1147B	Bypass upper esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D114J6	Bypass upper esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D114J9	Bypass upper esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D114JA	Bypass upper esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D114JB	Bypass upper esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D114K6	Bypass upper esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D114K9	Bypass upper esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D114KA	Bypass upper esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D114KB	Bypass upper esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D114Z6	Bypass upper esophagus to stomach, percutaneous endoscopic approach
0D114Z9	Bypass upper esophagus to duodenum, percutaneous endoscopic approach
0D114ZA	Bypass upper esophagus to jejunum, percutaneous endoscopic approach
0D114ZB	Bypass upper esophagus to ileum, percutaneous endoscopic approach
0D12476	Bypass middle esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D12479	Bypass middle esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1247A	Bypass middle esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1247B	Bypass middle esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D124J6	Bypass middle esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D124J9	Bypass middle esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D124JA	Bypass middle esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D124JB	Bypass middle esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D124K6	Bypass middle esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D124K9	Bypass middle esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D124KA	Bypass middle esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D124KB	Bypass middle esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D124Z6	Bypass middle esophagus to stomach, percutaneous endoscopic approach
0D124Z9	Bypass middle esophagus to duodenum, percutaneous endoscopic approach
0D124ZA	Bypass middle esophagus to jejunum, percutaneous endoscopic approach
0D124ZB	Bypass middle esophagus to ileum, percutaneous endoscopic approach
0D13476	Bypass lower esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D13479	Bypass lower esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1347A	Bypass lower esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1347B	Bypass lower esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D134J6	Bypass lower esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D134J9	Bypass lower esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach
0D134JA	Bypass lower esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D134JB	Bypass lower esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D134K6	Bypass lower esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D134K9	Bypass lower esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D134KA	Bypass lower esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D134KB	Bypass lower esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D134Z6	Bypass lower esophagus to stomach, percutaneous endoscopic approach
0D134Z9	Bypass lower esophagus to duodenum, percutaneous endoscopic approach
0D134ZA	Bypass lower esophagus to jejunum, percutaneous endoscopic approach
0D134ZB	Bypass lower esophagus to ileum, percutaneous endoscopic approach
0D15476	Bypass esophagus to stomach with autologous tissue substitute, percutaneous endoscopic approach
0D15479	Bypass esophagus to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1547A	Bypass esophagus to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1547B	Bypass esophagus to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D154J6	Bypass esophagus to stomach with synthetic substitute, percutaneous endoscopic approach
0D154J9	Bypass esophagus to duodenum with synthetic substitute, percutaneous endoscopic approach

0D154JA	Bypass esophagus to jejunum with synthetic substitute, percutaneous endoscopic approach
0D154JB	Bypass esophagus to ileum with synthetic substitute, percutaneous endoscopic approach
0D154K6	Bypass esophagus to stomach with nonautologous tissue substitute, percutaneous endoscopic approach
0D154K9	Bypass esophagus to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D154KA	Bypass esophagus to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D154KB	Bypass esophagus to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D154Z6	Bypass esophagus to stomach, percutaneous endoscopic approach
0D154Z9	Bypass esophagus to duodenum, percutaneous endoscopic approach
0D154ZA	Bypass esophagus to jejunum, percutaneous endoscopic approach
0D154ZB	Bypass esophagus to ileum, percutaneous endoscopic approach
0D16479	Bypass stomach to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1647A	Bypass stomach to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1647B	Bypass stomach to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1647L	Bypass stomach to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D164J9	Bypass stomach to duodenum with synthetic substitute, percutaneous endoscopic approach
0D164JA	Bypass stomach to jejunum with synthetic substitute, percutaneous endoscopic approach
0D164JB	Bypass stomach to ileum with synthetic substitute, percutaneous endoscopic approach
0D164JL	Bypass stomach to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D164K9	Bypass stomach to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D164KA	Bypass stomach to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D164KB	Bypass stomach to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D164KL	Bypass stomach to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D164Z9	Bypass stomach to duodenum, percutaneous endoscopic approach
0D164ZA	Bypass stomach to jejunum, percutaneous endoscopic approach
0D164ZB	Bypass stomach to ileum, percutaneous endoscopic approach
0D164ZL	Bypass stomach to transverse colon, percutaneous endoscopic approach
0D19479	Bypass duodenum to duodenum with autologous tissue substitute, percutaneous endoscopic approach
0D1947A	Bypass duodenum to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1947B	Bypass duodenum to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1947L	Bypass duodenum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D194J9	Bypass duodenum to duodenum with synthetic substitute, percutaneous endoscopic approach
0D194JA	Bypass duodenum to jejunum with synthetic substitute, percutaneous endoscopic approach
0D194JB	Bypass duodenum to ileum with synthetic substitute, percutaneous endoscopic approach
0D194JL	Bypass duodenum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D194K9	Bypass duodenum to duodenum with nonautologous tissue substitute, percutaneous endoscopic approach
0D194KA	Bypass duodenum to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D194KB	Bypass duodenum to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D194KL	Bypass duodenum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D194Z9	Bypass duodenum to duodenum, percutaneous endoscopic approach
0D194ZA	Bypass duodenum to jejunum, percutaneous endoscopic approach
0D194ZB	Bypass duodenum to ileum, percutaneous endoscopic approach
0D194ZL	Bypass duodenum to transverse colon, percutaneous endoscopic approach
0D1A47A	Bypass jejunum to jejunum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47B	Bypass jejunum to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47H	Bypass jejunum to cecum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47K	Bypass jejunum to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47L	Bypass jejunum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47M	Bypass jejunum to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47N	Bypass jejunum to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1A47P	Bypass jejunum to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1A47Q	Bypass jejunum to anus with autologous tissue substitute, percutaneous endoscopicapproach
0D1A4JA	Bypass jejunum to jejunum with synthetic substitute, percutaneous endoscopic approach
0D1A4JB	Bypass jejunum to ileum with synthetic substitute, percutaneous endoscopic approach
0D1A4JH	Bypass jejunum to cecum with synthetic substitute, percutaneous endoscopic approach
0D1A4JK	Bypass jejunum to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JL	Bypass jejunum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JM	Bypass jejunum to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JN	Bypass jejunum to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1A4JP	Bypass jejunum to rectum with synthetic substitute, percutaneous endoscopic approach
0D1A4JQ	Bypass jejunum to anus with synthetic substitute, percutaneous endoscopic approach
0D1A4KA	Bypass jejunum to jejunum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KB	Bypass jejunum to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KH	Bypass jejunum to cecum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KK	Bypass jejunum to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach

0D1A4KL	Bypass jejunum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KM	Bypass jejunum to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KN	Bypass jejunum to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KP	Bypass jejunum to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4KQ	Bypass jejunum to anus with nonautologous tissue substitute, percutaneous endoscopic approach
0D1A4ZA	Bypass jejunum to jejunum, percutaneous endoscopic approach
0D1A4ZB	Bypass jejunum to ileum, percutaneous endoscopic approach
0D1A4ZH	Bypass jejunum to cecum, percutaneous endoscopic approach
0D1A4ZK	Bypass jejunum to ascending colon, percutaneous endoscopic approach
0D1A4ZL	Bypass jejunum to transverse colon, percutaneous endoscopic approach
0D1A4ZM	Bypass jejunum to descending colon, percutaneous endoscopic approach
0D1A4ZN	Bypass jejunum to sigmoid colon, percutaneous endoscopic approach
0D1A4ZP	Bypass jejunum to rectum, percutaneous endoscopic approach
0D1A4ZQ	Bypass jejunum to anus, percutaneous endoscopic approach
0D1B47B	Bypass ileum to ileum with autologous tissue substitute, percutaneous endoscopic approach
0D1B47H	Bypass ileum to cecum with autologous tissue substitute, percutaneous endoscopic approach
0D1B47K	Bypass ileum to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47L	Bypass ileum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47M	Bypass ileum to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47N	Bypass ileum to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1B47P	Bypass ileum to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1B47Q	Bypass ileum to anus with autologous tissue substitute, percutaneous endoscopic approach
0D1B4JB	Bypass ileum to ileum with synthetic substitute, percutaneous endoscopic approach
0D1B4JH	Bypass ileum to cecum with synthetic substitute, percutaneous endoscopic approach
0D1B4JK	Bypass ileum to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JL	Bypass ileum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JM	Bypass ileum to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JN	Bypass ileum to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1B4JP	Bypass ileum to rectum with synthetic substitute, percutaneous endoscopic approach
0D1B4JQ	Bypass ileum to anus with synthetic substitute, percutaneous endoscopic approach
0D1B4KB	Bypass ileum to ileum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KH	Bypass ileum to cecum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KK	Bypass ileum to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KL	Bypass ileum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KM	Bypass ileum to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KN	Bypass ileum to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KP	Bypass ileum to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4KQ	Bypass ileum to anus with nonautologous tissue substitute, percutaneous endoscopic approach
0D1B4ZB	Bypass ileum to ileum, percutaneous endoscopic approach
0D1B4ZH	Bypass ileum to cecum, percutaneous endoscopic approach
0D1B4ZK	Bypass ileum to ascending colon, percutaneous endoscopic approach
0D1B4ZL	Bypass ileum to transverse colon, percutaneous endoscopic approach
0D1B4ZM	Bypass ileum to descending colon, percutaneous endoscopic approach
0D1B4ZN	Bypass ileum to sigmoid colon, percutaneous endoscopic approach
0D1B4ZP	Bypass ileum to rectum, percutaneous endoscopic approach
0D1B4ZQ	Bypass ileum to anus, percutaneous endoscopic approach
0D1H47H	Bypass cecum to cecum with autologous tissue substitute, percutaneous endoscopic approach
0D1H47K	Bypass cecum to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47L	Bypass cecum to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47M	Bypass cecum to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47N	Bypass cecum to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1H47P	Bypass cecum to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1H4JH	Bypass cecum to cecum with synthetic substitute, percutaneous endoscopic approach
0D1H4JK	Bypass cecum to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JL	Bypass cecum to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JM	Bypass cecum to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JN	Bypass cecum to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1H4JP	Bypass cecum to rectum with synthetic substitute, percutaneous endoscopic approach
0D1H4KH	Bypass cecum to cecum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KK	Bypass cecum to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KL	Bypass cecum to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KM	Bypass cecum to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KN	Bypass cecum to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1H4KP	Bypass cecum to rectum with nonautologous tissue substitute, percutaneous endoscopic approach

0D1H4ZH	Bypass cecum to cecum, percutaneous endoscopic approach
0D1H4ZK	Bypass cecum to ascending colon, percutaneous endoscopic approach
0D1H4ZL	Bypass cecum to transverse colon, percutaneous endoscopic approach
0D1H4ZM	Bypass cecum to descending colon, percutaneous endoscopic approach
0D1H4ZN	Bypass cecum to sigmoid colon, percutaneous endoscopic approach
0D1H4ZP	Bypass cecum to rectum, percutaneous endoscopic approach
0D1K47K	Bypass ascending colon to ascending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47L	Bypass ascending colon to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47M	Bypass ascending colon to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47N	Bypass ascending colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1K47P	Bypass ascending colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1K4JK	Bypass ascending colon to ascending colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JL	Bypass ascending colon to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JM	Bypass ascending colon to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JN	Bypass ascending colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1K4JP	Bypass ascending colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1K4KK	Bypass ascending colon to ascending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KL	Bypass ascending colon to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KM	Bypass ascending colon to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KN	Bypass ascending colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4KP	Bypass ascending colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1K4ZK	Bypass ascending colon to ascending colon, percutaneous endoscopic approach
0D1K4ZL	Bypass ascending colon to transverse colon, percutaneous endoscopic approach
0D1K4ZM	Bypass ascending colon to descending colon, percutaneous endoscopic approach
0D1K4ZN	Bypass ascending colon to sigmoid colon, percutaneous endoscopic approach
0D1K4ZP	Bypass ascending colon to rectum, percutaneous endoscopic approach
0D1L47L	Bypass transverse colon to transverse colon with autologous tissue substitute, percutaneous endoscopic approach
0D1L47M	Bypass transverse colon to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1L47N	Bypass transverse colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1L47P	Bypass transverse colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1L4JL	Bypass transverse colon to transverse colon with synthetic substitute, percutaneous endoscopic approach
0D1L4JM	Bypass transverse colon to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1L4JN	Bypass transverse colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1L4JP	Bypass transverse colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1L4KL	Bypass transverse colon to transverse colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4KM	Bypass transverse colon to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4KN	Bypass transverse colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4KP	Bypass transverse colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1L4ZL	Bypass transverse colon to transverse colon, percutaneous endoscopic approach
0D1L4ZM	Bypass transverse colon to descending colon, percutaneous endoscopic approach
0D1L4ZN	Bypass transverse colon to sigmoid colon, percutaneous endoscopic approach
0D1L4ZP	Bypass transverse colon to rectum, percutaneous endoscopic approach
0D1M47M	Bypass descending colon to descending colon with autologous tissue substitute, percutaneous endoscopic approach
0D1M47N	Bypass descending colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1M47P	Bypass descending colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1M4JM	Bypass descending colon to descending colon with synthetic substitute, percutaneous endoscopic approach
0D1M4JN	Bypass descending colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1M4JP	Bypass descending colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1M4KM	Bypass descending colon to descending colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1M4KN	Bypass descending colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1M4KP	Bypass descending colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1M4Z4	Bypass descending colon to cutaneous, percutaneous endoscopic approach
0D1M4ZM	Bypass descending colon to descending colon, percutaneous endoscopic approach
0D1M4ZN	Bypass descending colon to sigmoid colon, percutaneous endoscopic approach
0D1M4ZP	Bypass descending colon to rectum, percutaneous endoscopic approach
0D1N47N	Bypass sigmoid colon to sigmoid colon with autologous tissue substitute, percutaneous endoscopic approach
0D1N47P	Bypass sigmoid colon to rectum with autologous tissue substitute, percutaneous endoscopic approach
0D1N4JN	Bypass sigmoid colon to sigmoid colon with synthetic substitute, percutaneous endoscopic approach
0D1N4JP	Bypass sigmoid colon to rectum with synthetic substitute, percutaneous endoscopic approach
0D1N4KN	Bypass sigmoid colon to sigmoid colon with nonautologous tissue substitute, percutaneous endoscopic approach
0D1N4KP	Bypass sigmoid colon to rectum with nonautologous tissue substitute, percutaneous endoscopic approach
0D1N4ZN	Bypass sigmoid colon to sigmoid colon, percutaneous endoscopic approach
0D1N4ZP	Bypass sigmoid colon to rectum, percutaneous endoscopic approach
0WQF3ZZ	Repair abdominal wall, percutaneous approach

0WQF4ZZ	Repair abdominal wall, percutaneous endoscopic approach
0YQ53ZZ	Repair right inguinal region, percutaneous approach
0YQ54ZZ	Repair right inguinal region, percutaneous endoscopic approach
0YQ63ZZ	Repair left inguinal region, percutaneous approach
0YQ64ZZ	Repair left inguinal region, percutaneous endoscopic approach
0YQ73ZZ	Repair right femoral region, percutaneous approach
0YQ74ZZ	Repair right femoral region, percutaneous endoscopic approach
0YQ83ZZ	Repair left femoral region, percutaneous approach
0YQ84ZZ	Repair left femoral region, percutaneous endoscopic approach
0YQA3ZZ	Repair bilateral inguinal region, percutaneous approach
0YQA4ZZ	Repair bilateral inguinal region, percutaneous endoscopic approach
0YQE3ZZ	Repair bilateral femoral region, percutaneous approach
0YQE4ZZ	Repair bilateral femoral region, percutaneous endoscopic approach
0D18478	Bypass small intestine to small intestine with autologous tissue substitute, percutaneous endoscopic approach
0D184J8	Bypass small intestine to small intestine with synthetic substitute, percutaneous endoscopic approach
0D184K8	Bypass small intestine to small intestine with nonautologous tissue substitute, percutaneous endoscopic approach
0D184Z8	Bypass small intestine to small intestine, percutaneous endoscopic approach

BILLING CODE 4120–01–C

Per the applicant, oxygen saturation endoscopic imaging would not be necessary, as both imaging procedures are used to evaluate vascular perfusion and therefore the applicant excluded cases with the ICD–10–PCS procedure code 4A1BXSH (Monitoring of Gastrointestinal Vascular Perfusion using Indocyanine Green Dye, External Approach). In addition, the applicant compared cases with procedure code 4A1BXSH to cases without procedure code 4A1BXSH and found that cases with the procedure code have higher total standardized charges. The applicant further limited the cases to MS–DRGs with at least one percent of case volume, leaving 12,020 cases spread across 16 MS–DRGs, or 83 percent of the 14,522 cases initially identified. The applicant standardized the charges and applied an inflation factor of 13.2 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges from FY 2019 to FY 2021 (85 FR 59039). The applicant did not remove charges for the current technology as the applicant believed the use of EP–87000X System would not replace any other therapies except for the vascular perfusion monitoring procedure for which cases were already excluded.

The applicant then added charges for the new technology. The applicant explained that the total cost of the EP–87000X System consists of the capital equipment as well as a service contract for the equipment and a calibration fee required to perform a calibration between a video laparoscope and light source every 6 months. The applicant stated that it calculated the equipment cost per minute using the Medicare physician fee schedule formula used for calculating practice expense relative value units (RVUs). The applicant stated that it also assumed a 3 percent usage rate, a 5.5 percent interest rate, a 0 percent maintenance factor (as the maintenance fee is built into the cost of the equipment), and a 5-year useful life. The applicant multiplied the machine cost per minute by the number of minutes of procedure time, which the applicant estimated to be 4.5 hours or 270 minutes, to obtain the per patient cost. The applicant then converted the cost to charges by dividing the cost per patient by the national average cost-to-charge ratio for supplies and equipment (0.297).

Based on the cost information, the applicant calculated a final inflated case-weighted average standardized charge per case of $106,603 and an average case-weighted threshold of $80,392. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

As noted previously, because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs. Based on preliminary information from the applicant, it appears that the costs of the FUJIFILM EP–7000X System do not include any operating costs. Therefore, even if the technology meets the cost criterion, it appears that no new technology add-on payment would be made for the FUJIFILM EP–7000X System because, as discussed in prior rulemaking and noted previously, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). However, we are inviting public comments on whether the FUJIFILM EP–7000X System has any operating costs. If the FUJIFILM EP–7000X System does have operating costs, since it appears to meet the cost criterion as previously noted, we are proposing to approve new technology add-on payments for only the operating costs of the FUJIFILM EP–7000X System for FY 2022, subject to the technology receiving FDA marketing authorization for endoscopic observation, diagnosis, treatment, and image recording in patients requiring such procedures by July 1, 2021.

(7) Harmony™ Transcatheter Pulmonary Valve (TPV) System

Medtronic submitted an application for new technology-add on payments for Harmony™ Transcatheter Pulmonary Valve (TPV) System (''Harmony™'') for FY 2022. The system consists of a bioprosthetic heart valve developed from porcine pericardial tissue mounted on self-expanding nitinol struts sewn to a polyester fabric. According to the applicant, Harmony™ is implanted in the patient's heart between the right ventricle and the bifurcation of the pulmonary arteries to treat patients with congenital heart disease who are indicated for a pulmonary valve replacement. The applicant states that Harmony™ is the first transcatheter pulmonary valve that is designed to treat the patient's condition at the native site of the pulmonary valve without a pre-existing valve conduit or pre-existing bioprosthetic valve.

The Harmony™ TPV System received designation as a Breakthrough Device on

May 1, 2019, with the indication for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract. The applicant anticipates receiving 510(k) clearance for Class III medical device by June 2021. Additionally, the applicant noted that the proposed indication for the pending FDA marketing authorization is more expansive than the indication for the FDA Breakthrough Device status, to include patients who have had a prior transcatheter intervention. We note that under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of the Harmony™ TPV System for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022.

According to the applicant, there are currently no unique ICD–10–PCS codes describing the Harmony™ Transcatheter Pulmonary Valve (TPV). The applicant noted that the Harmony™ TPV System is currently reported within table 02R of the ICD–10 PCS tabular list (body part value Pulmonary Valve, approach value Percutaneous, device value as appropriate, and qualifier value No Qualifier). Per the applicant, this same code also applies to existing technology for transcatheter valve replacement within a conduit or a pre-existing prosthetic valve. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology.

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR dataset for claims representing patients with congenital diagnoses who received a surgical valve or a transcatheter procedure. The applicant identified claims across five MS–DRGs after excluding cases with outlier payments. Per the applicant, 6 percent of cases were in MS–DRG 216, 24 percent of cases were in MS–DRG 219, 12 percent of cases were in MS–DRG 220, 26 percent of cases were in MS–DRG 266, and 32 percent of cases were in MS–DRG 267. The applicant did not provide case counts because the volume in each MS–DRG was fewer than 11 cases.

Next, the applicant removed charges for the prior technology and standardized the charges. The applicant described the charges for the technology that would be replaced as ''the sum of the medical-surgical pacemaker amount, the intraocular lens amount, the other implants amount, and the investigational device amount.'' The applicant also removed charges related to the prior technology, which it described as ''the sum of the medical surgical supplies amount, the durable medical equipment amount, and the used durable medical amount minus the prior technology charges.'' The applicant then applied an inflation factor of 13.1 percent, which per the applicant is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule, to update the charges from FY 2019 to FY 2021. We note that the applicant appears to have used the FY 2021 IPPS/LTCH PPS proposed rule inflation factor rather than the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule of 13.2 percent (85 FR 59039), which would have resulted in a higher inflated charge figure. The applicant added charges for the new technology by dividing the cost of the Harmony™ TPV by the national CCR for implantable devices, which is 0.293 (85 FR 58601). The applicant also added charges related to the new technology, which the applicant estimated to be similar to the charges related to transcatheter procedures within MS–DRGs 266–267.

The applicant calculated a final inflated case-weighted average standardized charge per case of $257,970 and an average case-weighted threshold of $202,037. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We are concerned that the applicant's charge threshold analysis utilized a small sample of 55 cases, given that the applicant projected a case volume of over 1,000 cases for FY 2022. Subject to the applicant adequately addressing this concern, we would agree that the technology meets the cost criterion and therefore are proposing to approve Harmony™ Transcatheter Pulmonary Valve (TPV) System for new technology add-on payments for FY 2022, subject to the technology receiving FDA marketing authorization for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract by July 1, 2021. As noted previously, only the use of the Harmony™ TPV System for the treatment of symptomatic severe pulmonary regurgitation in patients with a surgically-repaired right ventricular outflow tract, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the Harmony™ Transcatheter Pulmonary Valve (TPV) System is $41,500. Per the applicant, this cost is comprised of $33,000 for the Harmony™ TPV and $8,500 for the Harmony™ transcatheter pulmonary valve delivery and loading system. It is not clear to us whether these costs reflect the use of capital equipment. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, if both components of the Harmony™ Transcatheter Pulmonary Valve (TPV) System are operating costs, we are proposing that the maximum new technology add-on payment for a case involving the use of the Harmony™ Transcatheter Pulmonary Valve (TPV) System would be $26,975 for FY 2022 (that is 65 percent of the average cost of the technology).

We are inviting public comments on whether the Harmony™ Transcatheter Pulmonary Valve (TPV) System meets the cost criterion and our proposal to approve new technology add-on payments for Harmony™ Transcatheter Pulmonary Valve (TPV) System for FY 2022, subject to FDA marketing authorization of Harmony™ Transcatheter Pulmonary Valve (TPV) System by July 1, 2021 for the treatment of patients with severe pulmonary regurgitation who have had prior intervention on the right ventricular outflow tract and are clinically indicated for a pulmonary valve replacement. We are also inviting public comment on whether the costs of the Harmony™ TPV and Harmony™ transcatheter pulmonary valve delivery and loading system reflect use of capital equipment.

(8) Neovasc Reducer™

Neovasc Inc. submitted an application for new technology-add on payments for the Neovasc Reducer™ System for FY 2022. The Neovasc Reducer™ System is a permanent implant inserted percutaneously into the coronary sinus and indicated for relief of angina symptoms in patients with refractory

angina. According to the applicant, the device creates a permanent and controlled narrowing of the coronary sinus to improve perfusion to ischemic myocardium with its hourglass shape. Per the applicant, the focal narrowing works to generate a pressure gradient and redistribute blood flow to ischemic areas of the heart.

The Neovasc Reducer™ System was designated as a Breakthrough Device on October 10, 2018, indicated for use in patients with refractory angina pectoris despite guideline-directed medical therapy who are unsuitable for revascularization by coronary artery bypass grafting (CABG) or by percutaneous coronary intervention (PCI), and anticipates receiving Pre-Market Approval as a Class III medical device in the first half of 2021.

According to the applicant, there are no unique ICD–10–PCS procedure codes to report the implantation of the device; however, the applicant noted that facilities could report the insertion of the Reducer™ System with ICD–10–PCS code 02H43DZ (Insertion of intraluminal device into coronary vein, percutaneous approach). Similarly, the applicant indicated that there are no unique ICD–10–CM diagnosis codes to report refractory angina; however, facilities might use ICD–10–CM diagnosis codes I20.8 'Other forms of angina pectoris' or I20.9 'Angina pectoris, unspecified' to report refractory angina. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for a new ICD–10–PCS procedure code for the implantation of the device and a new ICD–10–CM diagnosis code for refractory angina for FY 2022 to identify the technology.

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR dataset for claims with an ICD–10–PCS procedure code of 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) and 027034Z (Dilation of coronary artery, one artery with drug-eluting intraluminal device, percutaneous approach).

The applicant explained that patients who may be eligible for the Neovasc Reducer would be those diagnosed with refractory angina. The applicant further explained that because there is by definition no treatment for refractory angina, cases admitted to an inpatient hospital with a diagnosis of refractory angina were almost exclusively assigned to medical MS–DRGs that do not resemble a cardiac procedure in terms of clinical or resource use.

Per the applicant, Left Atrial Appendage (LAA) Occlusion is most closely related to the new technology, as it is a venous procedure using a permanent implant that is generally performed on a stable patient and requires a 1- to 2-day hospital stay. The applicant used the refractory angina cases to establish the eligible case count and the ratio between cases ''with complication and comorbidity (CC)'' and ''with major complication and comorbidity (MCC)'' versus cases ''without CC/MCC''. The applicant stated that it used this ratio to weight the MS–DRGs to which the LAA procedure cases mapped, as the refractory angina patient population differs in terms of comorbidities and severity of illness compared to the patient population receiving LAA.

The applicant identified a total of 16,182 LAA cases mapping to MS–DRGs 273 or 274. The applicant then removed the implantable device charges for the prior technology. The applicant also removed charges for cardiac catheterization, the operating room, and supplies and equipment. The applicant then standardized the charges and applied an inflation factor of 13.2 percent, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule (85 FR 89039), to update the charges from FY 2019 to FY 2021. The applicant added charges for the new technology, which it calculated by dividing the cost of the Reducer device by the national cost-to-charge ratio for implantable devices (0.239). The applicant noted that the charges for the new technology were not inflated.

As noted previously, the refractory angina patient population differs in terms of comorbidities and severity of illness compared to the patient population receiving LAA. Therefore, the applicant adjusted the volume weights for MS–DRGs 274/273 to reflect the refractory angina population. The applicant extracted cases with an ICD–10–CM diagnosis code I20.8 (Other forms of angina pectoris) and I20.9 (Angina pectoris, unspecified) from the FY 2019 MedPAR dataset. The applicant identified 9,548 cases with a refractory angina diagnosis spread across 513 MS–DRGs. The applicant divided cases into two groups—those mapping to an MS–DRG with a CC or MCC designation and those mapping to an MS–DRG without CC or MCC. The applicant found that the ratio of cases with CC/MCC to cases without CC/MCC was 61/39. The applicant applied this ratio to the refractory angina cases assigned to MS–DRGs with no CC/MCC designation and filled in the volumes by MS–DRG (39 percent of refractory angina cases were assigned to MS–DRG 274 and 61 percent to MS–DRG 273).

The applicant calculated a final inflated case-weighted average standardized charge per case of $141,304 and an average case-weighted threshold of $127,659. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the Neovasc Reducer™ System meets the cost criterion and therefore are proposing to approve the Neovasc Reducer™ System for new technology add-on payments for FY 2022, subject to the technology receiving FDA marketing authorization for use in patients with refractory angina pectoris despite guideline-directed medical therapy who are unsuitable for revascularization by CABG or by PCI by July 1, 2021.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the Neovasc Reducer™ System is $15,000. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Neovasc Reducer™ System would be $9,750 for FY 2022 (that is 65 percent of the average cost of the technology).

We are inviting public comments on whether the Neovasc Reducer™ System meets the cost criterion and our proposal to approve new technology add-on payments for Neovasc Reducer™ System for FY 2022, subject to the Neovasc Reducer™ receiving FDA marketing authorization by July 1, 2021 for use in patients with refractory angina pectoris despite guideline-directed medical therapy who are unsuitable for revascularization by coronary artery bypass grafting (CABG) or by percutaneous coronary intervention (PCI).

(9) Phagenyx® System

Phagenesis Ltd. submitted an application for new technology-add on payments for Phagenyx® System for FY 2022. The Phagenyx® system (Phagenyx®) is a neurostimulation device for the treatment of neurogenic dysphagia, which is often seen after

stroke, traumatic brain injury, or prolonged mechanical ventilation. Per the applicant, the system is comprised of a sterile single-use per patient catheter, introduced nasally and extending as far as the patient's stomach; and a base station, described as a touch screen user interface that facilitates the optimization of stimulation levels and stores patient and treatment information. Per the applicant, treatment involves the use of electric pulses to stimulate sensory nerves in the oropharynx.

The Phagenyx® system received Breakthrough Device designation on December 4, 2019 and anticipates receiving De Novo FDA clearance by the second quarter of CY 2021. Per the applicant, the FDA granted Breakthrough Device designation for use in treating neurogenic dysphagia in adult tracheotomized patients weaned from ventilation. The applicant noted that their De Novo application to FDA has a broader proposed indication, which states that it is intended for the treatment of non-progressive neurogenic dysphagia in adult patients, and explained that there are current plans to request an expanded Breakthrough Designation to align with this broader labelling. We note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of the Phagenyx® system for the treatment of neurogenic dysphagia in adult tracheotomized patients weaned from ventilation, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022, unless an expanded Breakthrough Designation that aligns with FDA labelling is also granted by the FDA marketing authorization deadline.

According to the applicant, there are currently no unique ICD–10–PCS codes describing the Phagenyx® system. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology.

With respect to the cost criterion, the applicant performed two analyses based on its Breakthrough Designation indication and the broader proposed indication. For both scenarios, the applicant used the FY 2019 MedPAR dataset to assess the MS–DRGs to which potential cases representing patients who may be eligible for the Phagenyx® System would most likely map. Under the first analysis based on the applicant's Breakthrough designation indication, the applicant searched for claims reporting an ICD–10–PCS procedure code for tracheostomy in combination with an ICD–10–CM diagnosis code for dysphagia.

Tracheostomy ICD-10-PCS Codes	
0B110F4	Bypass trachea to cutaneous with tracheostomy device, open approach
0B113F4	Bypass trachea to cutaneous with tracheostomy device, percutaneous approach
0B114F4	Bypass trachea to cutaneous with tracheostomy device, percutaneous endoscopic approach
0BW10FZ	Revision of tracheostomy device in trachea, open approach
0BW13FZ	Revision of tracheostomy device in trachea, percutaneous approach
0BW14FZ	Revision of tracheostomy device in trachea, percutaneous endoscopic approach
0BW17FZ	Revision of tracheostomy device in trachea, via natural or artificial opening
0BW18FZ	Revision of tracheostomy device in trachea, via natural or artificial opening endoscopic
0BW1XFZ	Revision of tracheostomy device in trachea, external approach
0B21XFZ	Change tracheostomy device in trachea, external approach

Dysphagia ICD-10-CM Codes	
R13.10	Unspecified
R13.12	Oropharyngeal phase
R13.13	Pharyngeal phase
R13.14	Pharyngoesophageal phase
R13.19	Other dysphagia

The applicant identified 8,181 cases spanning 170 MS–DRGs. Per the applicant, 69 percent of the discharges were in MS–DRGs 003 and 004, which is consistent with the applicant's assertion that cases involving tracheostomized patients typically map to these MS–DRGs.

Under the second analysis, based on the applicant's proposed broader indication, the applicant searched for claims reporting an ICD–10–CM diagnosis code for dysphagia, then excluded claims reporting an ICD–10–CM code for CNS disease. The applicant identified 390,328 cases spanning 722 MS–DRGs.

Dysphagia ICD-10-PCS Codes	Description
R13.10	Unspecified
R13.12	Oropharyngeal phase
R13.13	Pharyngeal phase
R13.14	Pharyngoesophageal phase
R13.19	Other dysphagia

CNS Disease ICD-10-CM Codes	Description
G10.x	Huntington's disease
G11.1x	Friedreich's ataxia
G12.x	Spinal muscular atrophy and related syndromes
G20.x	Parkinson's disease
G30xx	Alzheimer's disease
G31.83x	Lewy body disease
G35xx	Multiple sclerosis

Under both analyses, the applicant did not remove any charges for prior technology. The applicant standardized the charges and applied an inflation factor of 13.2 percent, or the 2-year inflation factor used to update the outlier threshold in the FY 2021 IPPS/LTCH final rule (85 FR 89039), to update the charges from FY 2019 to FY 2021. The applicant then added charges for the Phagenyx® System by dividing the cost by the national cost-to-charge ratio for supplies and equipment of 0.297 (85 FR 58601).

Under the analysis based on the applicant's Breakthrough Designation indication, the applicant calculated a final inflated case-weighted average standardized charge per case of $331,860 and an average case-weighted threshold of $276,624. Under the analysis based on the applicant's broader proposed indication, the applicant calculated a final inflated case-weighted average standardized charge per case of $104,346 and an average case-weighted threshold of $68,799. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that Phagenyx® System meets the cost criterion and therefore are proposing to approve Phagenyx® System for new technology add-on payments for FY 2022, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2021. As noted previously, only the use of the Phagenyx® System for the treatment of neurogenic dysphagia in adult tracheotomized patients weaned from ventilation, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the Phagenyx® System is $5,000. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Phagenyx® System would be $3,250 for FY 2022 (that is, 65 percent of the average cost of the technology).

We are inviting public comments on whether the Phagenyx® System meets the cost criterion and our proposal to approve new technology add-on payments for the Phagenyx® System for FY 2022 for the indication corresponding to the Breakthrough Device designation, subject to the Phagenyx® System receiving FDA marketing authorization for that indication by July 1, 2021.

(10) PRCFC

Cerus Corporation submitted an application for new technology-add on payments for FY 2022. PRCFC (pathogen reduced cryoprecipitated fibrinogen complex) is a blood product indicated for the treatment for fibrinogen deficiency-related bleeding, including massive hemorrhage. Per the applicant, this blood product is useful in emergency departments and operating rooms due to its 5-day shelf life at room temperature. The applicant stated that the 5-day shelf life of the blood product makes it immediately available in a ready-to-transfuse form as a fibrinogen source and thereby provides a significant benefit for patients with massive hemorrhage in a real time-critical fashion that is not achievable with other existing fibrinogen replacement products.

PRCFC is designated as a Breakthrough Device, indicated for control of massive bleeding associated with fibrinogen (Fg) deficiency, and received FDA premarket approval (PMA) on November 24, 2020 for the following indications: (1) Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency; (2) control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available; (3) second-line therapy for von Willebrand disease (vWD); and (4) control of uremic bleeding after other treatment modalities have failed. The applicant stated that the product will not be available for sale until the second quarter of CY 2021 due to manufacturing lead time for system components as well as validations and quality control analyses that must be completed by the manufacturing facilities. We note that, under the eligibility criteria for approval under the alternative pathway for certain

transformative new devices, only the use of PRCFC for the control of massive bleeding associated with fibrinogen (Fg) deficiency, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2022.

According to the applicant, there are currently no unique ICD–10–PCS codes that accurately identify the transfusion of this product. The applicant stated while there are many ICD–10–PCS codes to describe the transfusion of traditional nonautologous plasma cryoprecipitate, these codes do not apply to this product. The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology.

With respect to the cost criterion, the applicant searched the FY 2019 MedPAR dataset for cases reporting an ICD–10–PCS procedure code for nonautologous plasma cryoprecipitate. The applicant identified 8,553 cases spanning over 369 MS–DRGs.

30230M1	Transfusion of nonautologous plasma cryoprecipitate into Peripheral vein, open approach
30233M1	Transfusion of nonautologous plasma cryoprecipitate into peripheral vein, percutaneous approach
30240M1	Transfusion of nonautologous plasma cryoprecipitate into central vein, open approach
30243M1	Transfusion of nonautologous plasma cryoprecipitate into Central vein, percutaneous approach
30250M1	Transfusion of nonautologous plasma cryoprecipitate into peripheral artery, open approach
30253M1	Transfusion of nonautologous plasma cryoprecipitate into peripheral artery, percutaneous approach
30260M1	Transfusion of nonautologous plasma cryoprecipitate into central artery, open approach
30263M1	Transfusion of nonautologous plasma cryoprecipitate into central artery, percutaneous approach
30273M1	Transfusion of nonautologous plasma cryoprecipitate into products of conception, circulatory, percutaneous approach
30277M1	Transfusion of nonautologous plasma cryoprecipitate into products of conception, circulatory, via natural or artificial open approach

Per the applicant, the top 5 MS–DRGs were 219 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization with MCC), 220 (Cardiac Valve and Other Major Cardiothoracic Procedures Without Cardiac Catheterization with CC), 871 (Septicemia or Severe Sepsis Without Mv >96 Hours with MCC), 003 (ECMO or Tracheostomy with Mv >96 Hours Or Principal Diagnosis Except Face, Mouth And Neck With Major O.R. Procedure), and 216 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC) and accounted for 34 percent of all cases. The applicant then removed charges for the technology being replaced. Per the applicant, PRCFC would replace the current nonautologous plasma cryoprecipitate billed with a blood revenue code. The applicant explained that it could not separate nonautologous plasma cryoprecipitate from other blood charges and therefore removed all charges from the blood department. The applicant then standardized the charges and applied the 2-year outlier inflation factor of 13.2 percent used to update the outlier threshold in the FY 2021 IPPS/LTCH final rule (85 FR 59039). To estimate the cost of the technology, the applicant multiplied the sale price of PRCFC by an average of 12.9 units of cryoprecipitate required per patient, which the applicant asserted as equivalent to 5.2 grams of fibrinogen based on a recent study in adult cardiac surgery patients with clinically significant bleeding and fibrinogen deficiency.[930] The applicant estimated an average per-patient cost of $3,900, which the applicant converted to charges using the national cost-to-charge ratio for blood and blood products (0.271) from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant indicated that the outlier inflation factor was not applied to charges for PRCFC.

The applicant calculated a final inflated case-weighted average standardized charge per case of $299,895 and an average case-weighted threshold of $183,897. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that PRCFC meets the cost criterion and therefore are proposing to approve PRCFC for new technology add-on payments for FY 2022 when used for the control of massive bleeding associated with fibrinogen (Fg) deficiency. Based on preliminary information from the applicant at the time of this proposed rule, the cost of PRCFC is $750 per gram × 5.2 grams for the amount of $3,900 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of PRCFC would be $2,535 per patient for FY 2022 (that is, 65 percent of the average cost of the technology).

We are inviting public comments on whether PRCFC meets the cost criterion and our proposal to approve new technology add-on payments for PRCFC for FY 2022 when used for the control of massive bleeding associated with fibrinogen (Fg) deficiency.

(11) RECELL® Autologous Cell Harvesting Device

Avita Medical submitted an application for new technology-add on payments for RECELL® Autologous Cell Harvesting Device (RECELL®). The device is a standalone, single-use, battery-powered device used to process an autologous skin cell suspension for the treatment of acute thermal burn wounds. Per the applicant, the purpose of the device is to assist with harvesting a small graft from the patient's healthy skin and immediate processing into an autologous skin cell suspension which is then immediately applied to the patient's burn wound following surgical preparation of the acute thermal burn wound. The applicant describes the device components as including a mechanical scraping tray, wells for incubating the donor graft with a proprietary enzyme solution, a rinsing well, a cell strainer, a spray applicator as well as buttons for ''self-test'', and ''run.''

RECELL® was granted Expedited Access Pathway (EAP) by FDA (and is therefore considered part of the Breakthrough Devices Program by

[930] Callum J. et al. (2019). Effect of fibrinogen concentrate vs cryoprecipitate on blood component transfusion after cardiac surgery: The FIBRES randomized clinical trial. *JAMA, 322*(20), 1–11.

FDA [931]) on December 10, 2015 with the indication for use at the patient's point-of care for preparation of an autologous epithelial cell suspension to be applied to a prepared wound bed; under the supervision of a healthcare professional, the suspension is used to achieve epithelial regeneration for definitive closure of burn injuries, particularly in patients having limited availability of donor skin for autografting. RECELL® received FDA premarket approval (PMA) on September 20, 2018 with the indication for use listed as indicated for the treatment of acute thermal burn wounds in patients 18 years of age and older. Since the narrower indication for which the technology received PMA is included within the scope of the EAP indication, it appears that the PMA indication is appropriate for new technology add-on payment under the alternative pathway criteria. Per the applicant, RECELL® was available for sale upon FDA approval, albeit on a very limited basis primarily to burn centers involved with the clinical trials. According to the applicant, new ICD–10–PCS codes that are specific to RECELL® were created effective October 1, 2019. Per the applicant, the first three characters of these codes are ''0HR,'' followed by a fourth character signifying which body part is impacted, then ''X72'' for the final three characters.

With regard to the newness criterion, we believe that the beginning of the newness period for RECELL® commences from the date of approval by the FDA on September 20, 2018, as the applicant indicated the technology was available for sale from that date. Because the 3-year anniversary date of the entry of RECELL® onto the U.S. market (September 20, 2021) will occur in FY 2021, we do not believe that the device is eligible for new technology add on payments for FY 2022. Accordingly, we are proposing to disapprove RECELL® Autologous Cell Harvesting Device for new technology add on payments for FY 2022. We are inviting public comments on our proposal to disapprove new technology add-on payments for the RECELL Autologous Cell Harvesting Device for FY 2022, including on whether the technology meets the newness criterion.

We also present the applicant's analysis of the cost criterion for this application. With regard to the cost criterion, the applicant searched the FY 2019 MedPAR dataset for cases representing patients who may be eligible for treatment with RECELL®. The applicant noted that the FY 2019 MedPAR dataset did not contain the ICD–10–PCS code 0HR__X72 (Skin Replacement on the _____, Autologous Tissue Substitute, using Cell Suspension Technique) that identify RECELL® procedures because the code was first effective on October 1, 2019 after the closing date for the FY 2019 file. For purposes of this application, the applicant searched for cases reporting ICD–10–PCS codes 0HR_X73 (Skin Replacement on the _____, Autologous Tissue Substitute, Full Thickness) and 0HR__X74 (Skin Replacement on the _____, Autologous Tissue Substitute, Partial Thickness) which describe skin graft procedures used to treat burn injuries. The applicant highlighted the potential codes in between using the following table:

Character 1: O Medical and Surgical ***Character 2: H Skin and Breast*** ***Character 3: R Operation***			
Body Part	**Approach**	**Device**	**Qualifier**
0 Skin, Scalp 1 Skin, Face 2 Skin, Right Ear 3 Skin, Left Ear 4 Skin, Neck 5 Skin, Chest 6 Skin, Back 7 Skin, Abdomen 8 Skin, Buttock 9 Skin, Perineum A Skin, Inguinal B Skin, Right Upper Arm C Skin, Left Upper Arm D Skin, Right Lower Arm E Skin, Left Lower Arm F Skin, Right Hand G Skin, Left Hand H Skin, Right Upper Leg J Skin, Left Upper Leg K Skin, Right Lower Leg L Skin, Left Lower Leg M Skin, Right Foot N Skin, Left Foot	X External	7 Autologous Tissue Substitute	**2 Cell Suspension Technique** **3** Full Thickness **4** Partial Thickness

[931] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program.*

Per the applicant, skin grafts for burn diagnoses, including RECELL® procedures, are assigned to MS–DRGs 927, 928, and 929 in Major Diagnostic Category (MDC) 22 (Burns). No other MS–DRGs or MDCs were considered because RECELL® is only indicated for acute thermal burns. The applicant presented four analyses based on patient cases with increasingly conservative inputs to demonstrate that RECELL® meets the cost criterion. The applicant indicated that it varied the combination of the 2-year inflation factor from the FY 2021 IPPS/LTCH PPS final rule and charges for the new technology in each analysis.

For all four scenarios, the applicant calculated the average charge per case for each MS–DRG and then standardized the charges. The applicant did not remove any charges for the technology being replaced, as the applicant asserted that RECELL® is not replacing a technology. However, the applicant removed charges to account for a reduced length of stay because of utilizing RECELL®. The applicant applied the 2-year outlier inflation factor of 13.2 percent from the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021 for two analyses. To provide a conservative calculation, the applicant submitted two additional analyses that did not apply an inflation factor to standardized charges.

The applicant added charges for the new technology after dividing the cost of RECELL® by the national average cost-to-charge ratio for supplies and equipment (0.297). Per the applicant, the anticipated charges for RECELL® vary depending on the size and extent of the burn wound. The applicant noted that one RECELL® system covers up to 1,920 square centimeters of body surface area, which equals approximately 10 percent of the total body surface area (TBSA) of an average-sized adult. The applicant also noted the ICD–10–CM T21 diagnosis code category (Burn and corrosion of trunk) to describe the extent of a burn wound in 10 percent TBSA increments and provide an objective, claims-based index for the approximate number of RECELL® systems needed per patient. Per the applicant, more than one RECELL® system may be required to provide full coverage of the patient's burn wounds as indicated by the T31 diagnosis code category (Burns classified according to extent of body surface involved).

Burn Wound, % of Body Surface	Percent of Third-Degree Burn	ICD-10-CM Code	RECELL System Units Needed	Hospital Charge per Patient
Less than 10%	0-9%	T31.00XX	1	$25,252.53 ((1*$7,500)/0.297)
10% - 19%	0-9%	T31.10XX	2	$50,505.05 ((2*$7,500)/0.297)
	10-19%	T31.11XX	2	
20% - 29%	0-9%	T31.20XX	3	$75,757.58 ((3*$7,500)/0.297)
	10-19%	T31.21XX	3	
	20-29%	T31.22XX	3	
30% - 39%	0-9%	T31.30XX	4	$101,010.10 ((4*$7,500)/0.297)
	10-19%	T31.31XX	4	
	20-29%	T31.32XX	4	
	30-39%	T31.33XX	4	
40% - 50%	0-9%	T31.40XX	5	$126,262.63 ((5*$7,500)/0.297)
	10-19%	T31.41XX	5	
	20-29%	T31.42XX	5	
	30-39%	T31.43XX	5	
	40-49%	T31.44XX	5	
	50%	T31.50XX	5	

Under the first analysis, which involved a case with a 27 percent TBSA burn injury requiring three RECELL® systems and a 13.2 percent charge inflation factor, the applicant calculated a final inflated case-weighted average standardized charge per case of $268,119.

Under the second analysis, which involved the same case with a 27 percent TBSA burn injury requiring three RECELL® systems and no charge inflation factor, the applicant calculated a final inflated case-weighted average standardized charge per case of $245,824.

Under the third analysis, which involved a case with a 9 percent TBSA injury requiring one RECELL® system and a 13.2 percent charge inflation factor, the applicant calculated a final inflated case-weighted average standardized charge per case of $217,614.

Under the fourth analysis, which involved the same case with a 9 percent TBSA burn injury requiring one RECELL® system and no charge inflation factor, the applicant calculated a final inflated case-weighted average standardized charge per case of $195,319.

The applicant calculated a case-weighted threshold of $166,916 under all four analyses.

Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under all four analyses, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that RECELL® meets the cost criterion. As stated previously, because the 3-year anniversary date of the entry of RECELL® onto the U.S. market (September 20, 2021) will occur in FY

2021, we do not believe that the device is eligible for new technology add-on payments for FY 2022. Therefore, we are proposing to disapprove RECELL® for new technology add-on payments for FY 2022. However, in the event we receive updated information to establish that RECELL® meets the newness criterion, we are providing the following information regarding the new technology add-on payment amount.

Based on preliminary information from the applicant at the time of this proposed rule, the cost per patient of RECELL® is $15,000 or an estimated average cost of $7,500 per device multiplied by 2, which, per the applicant, is the average number of RECELL® units used per procedure. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. In the event we receive supplemental information to establish that the technology is still within the newness period, and we were to approve new technology add-on payments for RECELL® in the final rule, the maximum new technology add-on payment for RECELL® would be $9,570 for FY 2022 (that is, 65 percent of the average cost of the technology).

(12) Shockwave C2 Intravascular Lithotripsy (IVL) System

Shockwave Medical Inc. submitted an application for new technology-add on payments for Shockwave C2 Intravascular Lithotripsy (IVL) System for FY 2022. Per the applicant, the IVL Catheter is intended for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting. The applicant explained that the device is delivered through the coronary arterial system, and it generates intermittent sonic waves within the target treatment site that disrupt calcium within the lesion, allowing subsequent dilation of a coronary artery stenosis using low balloon pressure. The applicant also noted that the procedure can be used for otherwise difficult to treat calcified stenosis, including calcified stenosis that are anticipated to exhibit resistance to full balloon dilation or subsequent uniform coronary stent expansion.

Shockwave C2 Intravascular Lithotripsy (IVL) System was designated as a Breakthrough Device in August 2019, indicated for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting. The applicant stated that it anticipates receiving Pre-Market Approval as a Class III device from the FDA by March 2021 for the same proposed indication. The applicant stated that they expect to be shipping product within 1 month of FDA approval and state that they therefore estimate market availability by April 2021. According to the applicant, there are currently no unique ICD–10–PCS codes describing the device. The applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology.

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 81 percent of identified claims. To identify potential cases where Coronary IVL could be utilized, the applicant searched the FY 2019 MedPAR file for ICD–10–PCS codes for the placement of a coronary stent, consistent with the anticipated FDA indication for Shockwave C2 Intravascular Lithotripsy (IVL). The applicant included all codes beginning with ''027'' and ending with ''6'' or ''Z'' in its search. The applicant highlighted the potential codes in between using the table that follows:

Section: 0 Medical and Surgical *Body System: 2 Heart and Great Vessels* *Operation: 7 Dilation: expanding an orifice or the lumen of a tubular body part*			
Body Part	**Approach**	**Device**	**Qualifier**
0 Coronary Artery, One Artery **1 Coronary Artery, Two Arteries** **2 Coronary Artery, Three Arteries** **3 Coronary Artery, Four or More Arteries**	0 Open **3 Percutaneous** 4 Percutaneous Endoscopic	**4 Intraluminal Device, Drug-eluting** **5 Intraluminal Device, Drug-eluting, Two** **6 Intraluminal Device, Drug-eluting, Three** **7 Intraluminal Device, Drug-eluting, Four or More** **D Intraluminal Device** **E Intraluminal Device, Two** **F Intraluminal Device, Three** **G Intraluminal Device, Four or More** T Intraluminal Device, Radioactive Z No Device	**8 Bifurcation** **9** Z No Qualifier

For the analysis using 100 percent of cases, the applicant identified 160,901 cases mapping to 209 MS–DRGs. Per the applicant, Shockwave C2 Intravascular Lithotripsy (IVL) does not replace any current devices used for indicated patients. However, to be conservative, the applicant removed 50 percent of charges associated with revenue center 0278—other implants. The applicant then standardized the charges and applied the 2-year outlier inflation factor of 13.2 percent used to update the outlier threshold in the FY 2021 IPPS/LTCH final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. The applicant added charges for the new technology by multiplying the cost of the technology by the estimated number of devices per patient and then dividing by the national CCR for implantable devices (0.293) from the FY 2021 IPPS/LTCH PPS final rule. Under the analysis based on 100 percent of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $143,805 and an average case-weighted threshold of $115,693.

For the analysis using 81 percent of cases, the applicant identified 130,907 cases mapping to MS–DRGs 246 and 247. The applicant conducted the same analysis noted previously and determined a final inflated case-weighted average standardized charge per case of $122,020 and an average case-weighted threshold of $104,783. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that Shockwave C2 Intravascular Lithotripsy (IVL) System meets the cost criterion and therefore are proposing to approve Shockwave C2 Intravascular Lithotripsy (IVL) System for new technology add on payments for FY 2022, subject to the technology receiving FDA marketing authorization for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting by July 1, 2021.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the Shockwave C2 Intravascular Lithotripsy (IVL) System is $4,700 per device x 1.2 devices required per case for an amount of $5,640. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Shockwave C2 Intravascular Lithotripsy (IVL) System would be $3,666 for FY 2022 (that is, 65 percent of the average cost of the technology).

We are inviting public comments on whether the Shockwave C2 Intravascular Lithotripsy (IVL) System meets the cost criterion and our proposal to approve new technology add-on payments for the Shockwave C2 Intravascular Lithotripsy (IVL) System for FY 2022, subject to Shockwave C2 Intravascular Lithotripsy (IVL) System receiving FDA marketing authorization by July 1, 2021 for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting.

(13) Thoraflex™ Hybrid Device

Terumo Aortic submitted an application for new technology-add on payments for the Thoraflex™ Hybrid Device (Thoraflex™) for FY 2022. Per the applicant, the device is a sterile single-use, gelatin sealed Frozen Elephant Trunk (FET) surgical medical device. The applicant explained that the device is deployed through an opened aortic arch and then positioned into the descending thoracic aorta. The applicant further explained that, once it is completely deployed, the collar is sutured to the aorta, and graft anastomoses are then performed in a manner depending upon the chosen product design (which the applicant specified as either the Plexus or the Ante-Flo). The device includes a proximal crimped polyester surgical graft, central polyester collar, and distal nitinol ring stents supported by thin-wall polyester fabric. The applicant also noted that the device has a unique gelatin sealant that acts as a seal, preventing blood loss through the polyester fabric product wall.

Thoraflex™ Hybrid Device received Breakthrough Device designation on March 20, 2020 with an indication for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection. The applicant is seeking Pre-Market Approval for the device under a Class III device designation. The applicant stated there are currently no unique ICD–10–PCS codes that describe the Thoraflex™ Hybrid Device, but the following codes may be currently utilized: 02RX08Z (Replacement of thoracic aorta, ascending/arch with zooplastic tissue, open approach); 02RX0JZ (Replacement of thoracic aorta, ascending/arch with synthetic tissue, open approach); and 02RX0KZ (Replacement of thoracic aorta, ascending/arch with nonautologous tissue substitute, open approach). The applicant submitted a request to the ICD–10 Coordination and Maintenance Committee for approval of a unique code for FY 2022 to identify the technology.

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 74 percent of identified claims. To identify potential cases where the Thoraflex™ Hybrid Device could be utilized, the applicant searched the FY 2019 MedPAR file for claims reporting the ICD–10–PCS codes for thoracic aortic replacement procedures noted previously. For the analysis using 100 percent of cases, the applicant identified 5,374 cases mapping to 21 MS–DRGs. The applicant then removed charges for the technology being replaced. Per the applicant, the use of the Thoraflex™ Hybrid device is expected to replace a portion of prior technologies. The applicant explained that because an estimate of the percentage of these total charges that would be replaced could not be determined, it removed 100 percent of charges associated with medical/surgical supplies and devices (revenue centers 027x and 0624). The applicant then standardized the charges and applied the 2-year outlier inflation factor of 13.2 percent used to update the outlier threshold in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. As the average sales price of the Thoraflex™ has yet to be determined, the applicant did not add charges for the new technology. The applicant indicated that, once the price is determined, it will utilize the national cost-to-charge ratio for implantable devices from the FY 2021 IPPS/LTCH PPS final rule (0.293) to calculate estimated average hospital charges associated with the device. Under this analysis, based on 100 percent of identified claims, the applicant calculated a final inflated case-weighted average standardized charge per case of $298,047 and an average case-weighted threshold of $230,079.

Under the analysis based on 74 percent of cases, the applicant used the same methodology, which identified 3,978 cases across MS–DRGs 219 and 220. The applicant determined the average case-weighted threshold of $210,585 and a final inflated average standardized charge per case of $254,795. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the Thoraflex™ Hybrid Device meets the cost criterion and therefore are proposing to approve the Thoraflex™ Hybrid Device for new technology add-on payments for FY 2022, subject to the technology receiving FDA marketing authorization for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection by July 1, 2021.

The applicant has not provided an estimate for the cost of the Thoraflex™ Hybrid Device at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add on payment for the Thoraflex™ Hybrid Device would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

We are inviting public comments on whether the Thoraflex™ Hybrid Device meets the cost criterion and our proposal to approve new technology add-on payments for the Thoraflex™ Hybrid Device for FY 2022, subject to Thoraflex™ Hybrid Device receiving FDA marketing authorization by July 1, 2021 for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection.

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) CONTEPO™ (fosfomycin)

Nabriva Therapeutics US, Inc. submitted an application for new technology-add on payments for CONTEPO™ (fosfomycin) for FY 2022. CONTEPO™ is an intravenously administered epoxide antibiotic intended for the treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis (AP) caused by designated susceptible bacteria. Per the applicant, the drug inhibits cell wall synthesis at an earlier stage and provides new treatment for patients with cUTIs including acute pyelonephritis caused by *Escherichia coli* and *Klebsiella pneumonia* that have failed to respond to other first-line therapies.

CONTEPO™ is designated as a QIDP. The applicant initially applied for FDA approval when submitting a New Drug Application (NDA) in October 2018 seeking marketing approval of IV fosfomycin for injection (ZTI–01) for the treatment of patients 18 years and older with cUTI including acute pyelonephritis caused by designated susceptible bacteria. According to the applicant, on June 19, 2020, the FDA rejected the applicant's resubmitted NDA due to unresolved manufacturing issues that required an in-person inspection, which the FDA was not able to conduct due to travel restrictions. The applicant plans to resubmit an NDA

after discussing next steps with the FDA and hopes to receive FDA approval prior to July 1, 2021.

The applicant previously applied for a new technology add-on payment for the same indication for FY 2021 and received conditional approval for new technology add-on payments for FY 2021, subject to CONTEPO™ receiving FDA marketing authorization before July 1, 2021 (85 FR 58724). If CONTEPO™ receives FDA marketing authorization before July 1, 2021, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If the FDA marketing authorization is received on or after July 1, 2021, no new technology add-on payments will be made for cases involving the use of CONTEPO™ for FY 2021.

If CONTEPO™ receives FDA marketing authorization before July 1, 2021, the applicant has indicated that it would withdraw its application for FY 2022 and would instead seek new technology add-on payments for CONTEPO™ for FY 2022 as a continuation of the conditional approval for FY 2021. The applicant requested in its application for FY 2022 that if the technology does not receive FDA marketing authorization by July 1, 2021, CMS conditionally approve CONTEPO™ for new technology add-on payments for FY 2022.

The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™ in 2019. Effective October 1, 2019, CONTEPO™ administration can be identified by ICD–10–PCS procedure codes XW033K5 (Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) and XW043K5 (Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5), which the applicant states are unique to CONTEPO™ administration.

With regard to the cost criterion, the applicant used the FY 2019 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving CONTEPO™ would most likely be mapped. According to the applicant, CONTEPO™ is anticipated to be indicated for the treatment of hospitalized patients who have been diagnosed with complicated urinary tract infections (cUTIs). The applicant identified 199 ICD–10–CM diagnosis code combinations that identify hospitalized patients who have been diagnosed with a cUTI. Searching the FY 2019 MedPAR data file for these ICD–10–CM diagnosis codes resulted in a total of 525,876 potential cases that span 507 unique MS–DRGs. The applicant noted that the cases identified are fewer than in the FY 2021 new technology add-on payment application. Per the applicant, this change occurred because the applicant excluded additional claims for Medicare Advantage and inpatient ''full-encounter'' claims from all cohorts. The applicant maintained that while cohorts are smaller, the effects on the results were minimal.

The applicant examined associated charges per MS–DRG and removed charges for potential antibiotics that may be replaced by the use of CONTEPO™. Specifically, the applicant identified 5 antibiotics currently used for the treatment of patients who have been diagnosed with a cUTI and calculated the cost of each of these drugs for administration over 14-day inpatient hospitalization. Because patients who have been diagnosed with a cUTI would typically only be treated with one of these antibiotics at a time, the applicant estimated an average of the 14-day cost for the 5 antibiotics. The applicant then converted the cost to charges by dividing the costs by the national average CCR of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant then standardized the charges for each case and inflated each case's charges by applying the FY 2021 IPPS/LTCH PPS final rule outlier charge inflation factor of 13.2 percent (85 FR 59039).

The applicant then added the charges for the new technology by calculating the per-day cost per patient. The applicant noted that the duration of therapy of up to 14 days (patients that had a cUTI with concurrent bacteremia) is consistent with the prospective prescribing information, and that it used this 14-day duration of therapy to calculate total inpatient cost. The applicant then converted these costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). The applicant calculated a final inflated case-weighted average standardized charge per case of $79,619 and a case weighted threshold of $59,237. Because the final inflated case-weighted average standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant maintained it meets the cost criterion.

As summarized, the applicant used a 14-day duration of therapy to calculate total inpatient cost for purposes of its cost analysis. However, the applicant noted that the average number of days a patient would be administered CONTEPO™ will most likely fall between 10 to 14 days of therapy given the current guideline recommendations. Of these treatment days, the applicant noted that nearly all would occur during the inpatient hospital stay. Consistent with our historical practice, and as stated in the FY 2021 IPPS/LTCH PPS final rule, we believe the new technology add-on payment for CONTEPO™, if approved, would be based on the average cost of the technology and not the maximum (85 FR 58724). Without further information from the applicant regarding the average number of days CONTEPO™ is administered, we continue to believe using the middle ground of 12.5 days, based on the 10–14 day period indicated by the applicant, is appropriate for this analysis to determine the average number of days CONTEPO™ is administered in the hospital. To assess whether the technology would meet the cost criterion using an average cost for the technology based on this 12.5-day period for CONTEPO™ administration, we converted the costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.187 for drugs from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601). Based on data from the applicant, this resulted in a final inflated average case-weighted standardized charge per case of $77,613, which exceeds the case weighted threshold of $59,237.

Because of the large number of cases included in this cost analysis, the applicant supplemented the analysis as described previously with additional sensitivity analyses. In these analyses, the previous cost analysis was repeated using only the top 75 percent of cases and the top 20 MS–DRGs. In these two additional sensitivity analyses, the final inflated case-weighted average standardized charge per case for CONTEPO™ of $70,718 and $70,046 exceeded the average case-weighted threshold amount of $55,388 and $55,468, respectively. Because the final inflated case-weighted average standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant asserts that CONTEPO™ meets the cost criterion.

We agree with the applicant that CONTEPO™ (fosfomycin) meets the cost criterion.

Therefore, if CONTEPO™ does not receive FDA approval by July 1, 2021 to

receive new technology add on payments beginning with FY 2021, for FY 2022, per the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we are proposing to conditionally approve CONTEPO™ for new technology add-on payments, subject to the technology receiving FDA marketing authorization by July 1, 2022 (that is, by July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2022)). If CONTEPO™ receives FDA marketing authorization before July 1, 2022, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If the FDA marketing authorization is received on or after July 1, 2022, no new technology add-on payments would be made for cases involving the use of CONTEPO™ for FY 2022. As previously noted, the applicant has received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™. If CONTEPO™ receives FDA marketing authorization prior to July 1, 2021, we are proposing to continue making new technology add-on payments for CONTEPO™ in FY 2022.

As discussed previously, without further information from the applicant regarding the average number of days CONTEPO™ is administered, and consistent with our approach for the FY 2021 IPPS/LTCH PPS final rule, we believe using a 12.5-day duration of therapy is a reasonable approach for estimating the average cost of the technology. Based on preliminary information from the applicant at the time of this proposed rule, the cost of CONTEPO™ administered over 12.5 days is $3,500. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that if CONTEPO™ receives FDA marketing authorization prior to July 1, 2022, the maximum new technology add-on payment for a case involving the use of CONTEPO™ (fosfomycin) would be $2,625 for FY 2022 (that is, 75 percent of the average cost of the technology). Cases involving the use of CONTEPO™ that would be eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033K5 (Introduction of Fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043K5 (Introduction of Fosfomycin antiinfective into central vein, percutaneous approach, new technology group 5).

We are inviting public comments on whether CONTEPO™ (fosfomycin) meets the cost criterion and our proposal to approve new technology add-on payments for CONTEPO™ (fosfomycin) for FY 2022.

(2) FETROJA® (cefiderocol)

Shionogi & Co., Ltd submitted an application for new technology-add on payments for FETROJA® (cefiderocol) for FY 2022. FETROJA® is an injectable siderophore cephalosporin indicated for the treatment of hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP) on September 25, 2020. Per the applicant, FETROJA® should be used to treat infections where limited or no alternative treatment options are available and where FETROJA® (cefiderocol) is likely to be an appropriate treatment option, which may include use in patients with infections caused by documented or highly suspected carbapenem-resistant and/or multidrug-resistant gram-negative (GN) pathogens. The applicant asserts that the principal antibacterial/bactericidal activity of FETROJA® occurs with inhibiting GN bacterial cell wall synthesis by binding to penicillin-binding proteins.

FETROJA® was designated as a QIDP for HABP/VABP and received FDA marketing approval for this indication on September 25, 2020. FETROJA® became available on the market for the treatment of HABP/VABP after FDA approval for this indication. FETROJA® also has a QIDP designation and is FDA approved for cUTI, and was granted a new technology add-on payment under the alternative new technology add-on payment pathway for certain antimicrobials for this indication in the FY 2021 IPPS/LTCH final rule (85 FR 58721). The current new technology add-on payment application for FY2022 is specific to the indication of HABP/VABP. According to the applicant, the ICD–10 Coordination and Maintenance Committee approved the following ICD–10–PCS codes to specifically describe the IV administration of FETROJA, effective October 1, 2020: XW033A6 (Introduction of cefiderocol anti-infective into peripheral vein, percutaneous approach, new technology group 6) and XW043A6 (Introduction of cefiderocol anti-infective into central vein, percutaneous approach, new technology group 6).

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent and 75 percent of identified claims. For both scenarios, the applicant used the FY 2019 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for FETROJA® treatment would be mapped. The applicant identified eligible cases by searching the FY 2019 MedPAR for cases reporting ICD–10–CM codes for pneumonia and for resistance to antimicrobial drugs.

Under the first scenario of 100 percent of cases, the applicant identified 9,595 cases mapping to 203 MS–DRGs. Under the second scenario of 75 percent of cases, the applicant identified 7,218 cases mapping to 19 MS–DRGs. The applicant standardized the charges after calculating the average case-weighted unstandardized charge per case for both scenarios and removing 50 percent of charges associated with the drug revenue centers 025x, 026x, and 063x under both scenarios. Per the applicant, FETROJA® is expected to replace some of the drugs that would otherwise be utilized to treat these patients. The applicant stated that it believes 50 percent of these total charges to be a conservative estimate as other drugs will still be required for these patients during their hospital stay. The applicant then applied an inflation factor of 13.2 percent, which was the 2-year outlier charge inflation factor used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59039), to update the charges from FY 2019 to FY 2021. The applicant then added charges for FETROJA® by dividing the total average hospital cost of FETROJA® by the national average cost-to-charge ratio (0.187) for drugs published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601).

The applicant calculated a final inflated case-weighted average standardized charge per case of $164,825 for the first scenario and $148,821 for the second scenario and an average case-weighted threshold amount of $78,296 for the first scenario and $73,607 for the second scenario. Because the final inflated case-weighted average standardized charge per case for each scenario exceeds the average case-weighted threshold amount for each scenario, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that FETROJA® (cefiderocol) meets the cost criterion and therefore are proposing to approve FETROJA® for new technology

add on payments for FY 2022 when used for the treatment of HABP/VABP. Cases involving the use of FETROJA® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW03366 or XW04366.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of FETROJA® administered over an average of 10.4 days is $11,439.79. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of FETROJA® when used for the treatment of HABP/VABP would be $8,579.84 for FY 2022 (that is, 75 percent of the average cost of the technology).

We are inviting public comments on whether FETROJA® (cefiderocol) meets the cost criterion and our proposal to approve new technology add-on payments for FETROJA® for FY 2022 for the treatment of HABP/VABP.

(3) RECARBRIO™ (imipenem, cilastatin, and relebactam)

Merck & Co. submitted an application for new technology add-on payments for RECARBRIO™ for FY 2022. RECARBRIO™ is a fixed-dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel b-lactamase inhibitor (BLI) administered via intravenous infusion. Per the applicant, RECARBRIO™ is indicated for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible Gram-negative bacteria. RECARBRIO™ is also indicated for complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) and was approved for new technology add-on payment for these indications in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58728).

The applicant explained that the recommended dose of RECARBRIO™ is 1.25 grams administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CrCl) 90 mL/min or greater. Per the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose and 4 doses per day. Per RECARBRIO™'s prescribing information, the recommended duration of treatment is 4 days to 14 days.

RECARBRIO™ is designated as a QIDP indicated for the treatment of HABP/VABP and received FDA approval through a supplemental NDA on June 4, 2020 for this indication. According to the applicant, RECARBRIO™ originally submitted an NDA for the cUTI and cIAI indications and received FDA approval on July 16, 2019. The applicant previously applied for the new technology add-on payment for the cUTI and cIAI indications, which CMS approved in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58728). The application for new technology add-on payments for FY 2022 is specific to the HABP and VABP indications. The applicant noted that RECARBRIO™ can be identified with ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5).

To demonstrate that the technology meets the cost criterion, the applicant searched the FY 2019 MedPAR Limited Data Set (LDS) for cases reporting ICD–10–CM diagnosis code J95.851(Ventilator assisted pneumonia) for VABP, and the following list of codes for HABP:

Group	Code	Code Type	Description
Group 1	J181	ICD-10-CM Diagnosis Code	Lobar pneumonia, unspecified organism
Group 1	J150	ICD-10-CM Diagnosis Code	Pneumonia due to Klebsiella pneumoniae
Group 1	J151	ICD-10-CM Diagnosis Code	Pneumonia due to Pseudomonas
Group 1	J14	ICD-10-CM Diagnosis Code	Pneumonia due to Hemophilus influenzae
Group 1	J158	ICD-10-CM Diagnosis Code	Pneumonia due to other specified bacteria
Group 1	J155	ICD-10-CM Diagnosis Code	Pneumonia due to Escherichia coli
Group 1	J156	ICD-10-CM Diagnosis Code	Pneumonia due to other aerobic Gram-negative bacteria
Group 1	J158	ICD-10-CM Diagnosis Code	Pneumonia due to other specified bacteria
Group 1	J159	ICD-10-CM Diagnosis Code	Unspecified bacterial pneumonia
Group 1	J168	ICD-10-CM Diagnosis Code	Pneumonia due to other specified infectious organisms
Group 1	J17	ICD-10-CM Diagnosis Code	Pneumonia in diseases classified elsewhere
Group 1	J180	ICD-10-CM Diagnosis Code	Bronchopneumonia, unspecified organism
Group 1	J189	ICD-10-CM Diagnosis Code	Pneumonia, unspecified organism
Group 1	J9600	ICD-10-CM Diagnosis Code	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia
Group 1	J9690	ICD-10-CM Diagnosis Code	Respiratory failure, unspecified, whether with hypoxia or hypercapnia
Group 1	J9620	ICD-10-CM Diagnosis Code	Acute and chronic respiratory failure

Additionally, for HABP, the applicant identified cases that included present on admission indicators of N (Diagnosis was not present at time of inpatient admission), U (Documentation insufficient to determine if condition was present at the time of inpatient admission), W (Clinically undetermined), or 1 (Unreported/not used).

The applicant identified a total 106,964 cases, which were mapped to 355 unique MS–DRGs. The applicant removed 88 MS–DRGs with minimal frequencies (fewer than 11 cases), leaving 106,655 cases mapping to 267 MS–DRGs. Per the applicant, the top 10 MS–DRGs covered approximately 34.1 percent of all patients. The applicant examined associated charges per MS–DRG and removed all pharmacy charges to be replaced using RECARBRIO™. The applicant then standardized and inflated the charges by applying the FY 2021 IPPS/LTCH PPS final rule outlier

charge inflation factor of 1.13218 (85 FR 59039).

The applicant estimated an average cost of RECARBRIO™ for the treatment of HABP and VABP in the inpatient setting based on the recommended dose of 1.25 grams (imipenem 500 mg, cilastatin 500 mg, relebactam 250 mg) administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CLcr) 90 mL/min or greater. As stated previously, according to the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose, 4 doses per day within a recommended treatment duration of 4 to 14 days. To determine the cost per patient, the applicant stated it used the FY 2019 MedPAR analysis of total cases representing hospitalized patients who may be eligible for treatment involving RECARBRIO™ to identify a percentage of total cases per indication: HABP 94.07 percent of cases and VABP 5.93 percent. According to the applicant, it next identified the average length of stay per indication: HABP 14.2 days and VABP 24.2 days. The applicant also assumed that 70 percent of patients would receive RECARBRIO™ beginning on the fourth day after admission while the remaining 30 percent of these patients would receive RECARBRIO™ beginning on the second day of their hospitalization. The applicant then multiplied the daily dose cost by the two scenarios for each HABP and VABP indication to determine the cost per stay for each indication by days of drug use. Next it multiplied the cost per stay for each indication by the share of cases by days in use (70/30 percent split) to determine the weighted cost for days in use estimation. The applicant then summed the 70/30 percent case breakdown (weighted cost) for patients initiating on day 2 and 4 to determine the average cost per indication for HABP and VABP. Finally, the applicant multiplied the average cost per indication by the percent of total cases for HABP and VABP, then summed them to get the overall average cost. The applicant converted this cost to a charge by dividing the costs by the national average cost-to-charge ratio of 0.187 for drugs published in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58601) and added the resulting charges to determine the final inflated case-weighted average standardized charge per case.

The applicant calculated a final inflated case-weighted average standardized charge per case of $258,946 and an average case-weighted threshold amount of $123,172. The applicant also calculated an average case-weighted standardized charge per case for HABP and VABP separately using the same methodology previously described and determined final inflated case-weighted average standardized charges per case of $249,992 for HABP and $394,992 for VABP and average case-weighted thresholds of $117,466 for HABP and $214,869 for VABP.

In addition, because RECARBRIO™ was previously approved for a new technology add-on payment for the cUTI and cIAI indications, the applicant modified the added amount of the charge for RECARBRIO™ based on the cost calculation of the technology using all four indications. Using the same methodology previously described, the applicant determined final inflated case-weighted average standardized charges per case of $250,209 for HABP and VABP, $241,255 for HABP, and $386,255 for VABP and average case-weighted thresholds of $123,172 for HABP and VABP, $117,466 for HABP, and $214,869 for VABP. Because the final inflated case-weighted average standardized charge per case exceeded the average case-weighted threshold amount in each scenario, the applicant maintained that the technology met the cost criterion.

We agree with the applicant that RECARBRIO™ meets the cost criterion and therefore are proposing to approve RECARBRIO™ for new technology add on payments for FY 2022 when used for treatment of HABP and VABP. Based on preliminary information from the applicant at the time of this proposed rule, the cost of RECARBRIO™ is $12,768.68 when used for the treatment of HABP and VABP. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of RECARBRIO™ would be $9,576.51 for FY 2022 (that is, 75 percent of the average cost of the technology) when used for treatment of HABP and VABP.

We are inviting public comments on whether RECARBRIO™ (imipenem, cilastatin, and relebactam) meets the cost criterion and our proposal to approve new technology add-on payments for the RECARBRIO™ (imipenem, cilastatin, and relebactam) for the indications of HABP and VABP for FY 2022.

7. Comment Solicitation on the New Technology Add-On Payment Newness Period for Products Available Through an Emergency Use Authorization (EUA) for COVID–19

As noted previously, and explained in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights.

As we have discussed in prior rulemaking (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market, when data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In some specific circumstances, we have recognized a date later than FDA approval as the appropriate starting point for the 2-year to 3-year newness period for new technologies approved for add-on payments (85 FR 58734).

As discussed previously, in the FY 2009 IPPS final rule (73 FR 48561 through 48563), we revised our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. We stated that new technologies that have not received FDA approval do not meet the newness criterion. In addition, we stated we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before the FDA makes a determination as to whether the medical service or technology is safe and effective. For these reasons, we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We also finalized at 42 CFR 412.87(c) (subsequently redesignated as 412.87(e)) that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances, licensures, and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to § 412.87(e)(2) to indicate that new technologies must receive FDA marketing authorization (for example, pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; approval of a New Drug Application (NDA); or Biologics License Application (BLA) licensure) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As noted in the FY 2021 IPPS/LTCH PPS final rule, this technical clarification did not change our longstanding policy for evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, and we continue to consider FDA marketing authorization as representing that a product has received FDA approval or clearance for purposes of eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

An EUA by the FDA allows a product to be used for emergency use, but under our longstanding policy, we believe it would not be considered an FDA marketing authorization for the purpose of new technology add-on payments, as a product that is available only through an EUA is not considered to have an FDA approval or clearance. Therefore, under the current regulations at 42 CFR 412.87(e)(2) and consistent with our longstanding policy of not considering eligibility for new technology add-on payments prior to a product receiving FDA approval or clearance, we believe a product available only through an EUA would not be eligible for new technology add-on payments.

Although an EUA is not an FDA approval or clearance that would be considered FDA marketing authorization within the meaning of § 412.87(e)(2), data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance. CMS also recognizes that the manufacturers of products with EUAs (such as some COVID–19 treatments) might further engage with FDA to seek approval or clearance, and may be eligible for new technology add-on payments in the future. We are seeking comment on how data reflecting the costs of a product with an EUA, which may become available upon authorization of the product for emergency use (but prior to FDA approval or clearance), should be considered for purposes of the 2-year to 3-year period of newness for new technology add-on payments for a product with or expected to receive an EUA, including whether the newness period should begin with the date of the EUA.

8. Proposal To Extend the New COVID–19 Treatments Add-On Payment (NCTAP) Through the End of the FY in Which the PHE Ends for Certain Products and Discontinue NCTAP for Products Approved for New Technology Add-on Payments in FY 2022

In response to the COVID–19 PHE, we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157–71158). We believe that as drugs and biological products become available and are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of: (1) 65 percent of the operating outlier threshold for the claim; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.

We anticipate that there might be inpatient cases of COVID–19, beyond the end of the PHE, for which payment based on the assigned MS–DRG may not adequately reflect the additional cost of new COVID–19 treatments. In order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE, we believe that the NCTAP should remain available for cases involving eligible treatments for the remainder of the fiscal year in which the PHE ends (for example, if the PHE were to end in FY 2022, until September 30, 2022).[932] At the same time, we also believe that any new technology add-on payments that may be approved for a COVID–19 treatment would also serve to mitigate any potential financial disincentives for hospitals to provide that new COVID–19 treatment, such that the NCTAP would no longer be needed for that same product. We note that a COVID–19 treatment that is the subject of an application for FY 2022 new technology add-on payments and which receives FDA approval or clearance by July 1, 2021 would be eligible for consideration for new technology add-on payments for FY 2022.

Therefore, we are proposing to extend the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends (for example, September 30, 2022). We are also proposing to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022.

We believe this proposal to extend NCTAP for eligible products would allow some form of add-on payment (that is, NCTAP or new technology add-on payment) to continue uninterrupted for some period of time following the conclusion of the COVID–19 PHE, as we anticipate that there will continue to be inpatient cases of COVID–19 after the PHE ends. For example, if a drug or biological product with an EUA to treat COVID–19 does not receive FDA approval by July 1, 2021, and the PHE ends on December 31, 2021, this proposal would allow discharges involving that product to continue to be eligible for the NCTAP through September 30, 2022 (the end of FY 2022). If that same product receives FDA approval by July 1, 2022, it would be eligible for consideration of new technology add-on payments beginning FY 2023, and new technology add-on payments, if approved, would begin on October 1, 2022 (the beginning of FY 2023).

We invite public comment on our proposals to continue the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends and to discontinue the NCTAP for products that are approved for new technology add-on payments.

[932] On January 22, 2021, former Acting HHS Secretary Norris Cochran sent a letter to governors announcing that HHS has determined that the public health emergency will likely remain in place for the entirety of 2021, and when a decision is made to terminate the declaration or let it expire, HHS will provide states with 60 days' notice prior to termination.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2022 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050, which expires on March 31, 2022.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2022 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2022 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2022 wage index appears under sections III.E. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed FY 2022 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982)) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. Typically, interim OMB bulletins (those issued between decennial censuses) have only contained minor modifications to labor market delineations. However, the April 10, 2018 OMB Bulletin No. 18–03 and the September 14, 2018 OMB Bulletin No. 18–04 included more modifications to the labor market areas than are typical for OMB bulletins issued between decennial censuses, including some material modifications that had a number of downstream effects, such as reclassification changes. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and

Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2018, beginning with the FY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the FY 2021 IPPS/LTCH PPS final rule.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017 and July 1, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area, one new component of an existing Combined Statistical Area and changes to New England City and Town Area (NECTA) delineations. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58744), we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS proposed rule. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage index for FY 2022. Specifically, the updates consisted of changes to NECTA delineations and the creation of a new Micropolitan Statistical Area which was then added as a new component to an existing Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in FY 2021 IPPS/LTCH PPS final rule (85 FR 58746), we include hospitals located in Micropolitan Statistical areas in each State's rural wage index. Therefore, while we are proposing to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific wage index updates would not be necessary for FY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any hospital's geographic area for purposes of the wage index calculation for FY 2022.

For FY 2022, we would continue to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01 and 18–04.

We note that, in connection with our adoption in FY 2021 of the updates in OMB Bulletin 18–04, we adopted a policy to place a 5 percent cap, for FY 2021, on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020 so that a hospital's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58753 through 58755) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition is set to expire at the end of FY 2021. However, given the unprecedented nature of the ongoing COVID–19 PHE, we also seek comment on whether it would be appropriate to continue to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04. For example, such an extended transition could potentially take the form of holding the FY 2022 wage index for those hospitals harmless from any reduction relative to their FY 2021 wage index. If we were to apply a transition to the FY 2022 wage index for hospitals negatively impacted by our adoption of the updates in OMB Bulletin 18–04, we also seek comment on making this transition budget neutral, as is our usual practice, in the same manner that the FY 2021 transition was made budget neutral as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58755).

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

For FY 2022, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2022, Tables 2 and 3 associated with this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS code updates.

B. Worksheet S–3 Wage Data for the Proposed FY 2022 Wage Index

The proposed FY 2022 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2018 (the FY 2021 wage indexes were based on data from cost reporting periods beginning during FY 2017).

1. Included Categories of Costs

The proposed FY 2022 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2021, the proposed wage index for FY 2022 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2022 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

C. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2022 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB Control Number 0938–0050 with expiration date March 31, 2022) for cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018. For wage index purposes, we refer to cost reports during this period as the ''FY 2018 cost report,'' the ''FY 2018 wage data,'' or the ''FY 2018 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed final FY 2022 wage index includes FY 2018 data submitted to us as of February 5, 2021. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2022 wage index, we identified and excluded 86 providers with aberrant data that should not be included in the wage index. If data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2022 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 19, 2021.

In constructing the proposed FY 2022 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2018, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed rule, we removed 3 hospitals that converted to CAH status on or after January 24, 2020, the cut-off date for CAH exclusion from the FY 2021 wage index, and through and including January 24, 2021, the cut-off date for CAH exclusion from the FY 2022 wage index. In summary, we calculated the proposed FY 2021 wage index using the Worksheet S–3, Parts II and III wage data of 3,159 hospitals.

For the proposed FY 2022 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the proposed FY 2022 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 16 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

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CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
050121	0.85
05B121	0.15
070022	0.99
07B022	0.01
070033	0.93
07B033	0.07
100029	0.55
10B029	0.45
100167	0.55
10B167	0.45

CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
330195	0.89
33B195	0.11
330234	0.75
33B234	0.25
340115	0.95
34B115	0.05
360020	0.97
36B020	0.03
390006	0.94
39B006	0.06
390115	0.86
39B115	0.14
390142	0.83
39B142	0.17
450330	0.98
45B330	0.02
460051	0.81
46B051	0.19
510022	0.94
51B022	0.06
520009	0.71
52B009	0.29
670062	0.66
67B062	0.34

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We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third

position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the Proposed FY 2022 Unadjusted Wage Index

The method used to compute the proposed FY 2022 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761, September 18, 2020), and we are not proposing any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the proposed wage index (in this case, for FY 2022, these were data from cost reports for cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018). In addition, we included data from some hospitals that had cost reporting periods beginning before October 2017 and reported a cost reporting period covering all of FY 2018. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2018 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2018 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following:

(Lines 26 through 43 − Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).

- We compute overhead wage-related costs by multiplying the overhead hours

ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.

• We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2017 through April 15, 2019, for private industry hospital workers from the BLS' Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage of the ECI for FY 2022. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306) August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the proposed FY 2022 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306) August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of the Appendix of the proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Pub. L. 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306; August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2017, through April 15, 2019, for private industry hospital workers from the BLS' *Compensation and Working Conditions.* We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2022. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2017	11/15/2017	1.03317
11/14/2017	12/15/2017	1.03154
12/14/2017	01/15/2017	1.02988
01/14/2018	02/15/2018	1.02816
02/14/2018	03/15/2018	1.02638
03/14/2018	04/15/2018	1.02447
04/14/2018	05/15/2018	1.02238
05/14/2018	06/15/2018	1.02011
06/14/2018	07/15/2018	1.01780
07/14/2018	08/15/2018	1.01560
08/14/2018	09/15/2018	1.01350
09/14/2018	10/15/2018	1.01140
10/14/2018	11/15/2018	1.00920
11/14/2018	12/15/2018	1.00690
12/14/2018	01/15/2019	1.00456
01/14/2019	02/15/2019	1.00226
02/14/2019	03/15/2019	1.00000
03/14/2019	04/15/2019	0.99781

For example, the midpoint of a cost reporting period beginning January 1, 2018, and ending December 31, 2018, is June 30, 2018. An adjustment factor of 1.01780 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2017, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2022, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the methodology, as previously discussed, the proposed FY 2022 unadjusted national average hourly wage is the following:

Proposed FY 2022 Unadjusted National Average Hourly Wage	$46.42

E. Proposed Occupational Mix Adjustment to the FY 2022 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2019 Medicare Wage Index Occupational Mix Survey for the FY 2022 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), we collected data in 2016 to

compute the occupational mix adjustment for the FY 2019, FY 2020, and FY 2021 wage indexes. A new measurement of occupational mix is required for FY 2022.

The FY 2022 occupational mix adjustment is based on a new calendar year (CY) 2019 survey. Hospitals were required to submit their completed 2019 surveys (Form CMS–10079, OMB number 0938–0907, expiration date September 31, 2022) to their MACs by September 3, 2020. The preliminary, unaudited CY 2019 survey data were posted on the CMS website on September 8, 2020. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2022 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2022

For FY 2022, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the proposed FY 2022 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2022 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this proposed rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2022 wage index. For the proposed FY 2022 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,159 hospitals, and we used the occupational mix surveys of 2,955 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 94 percent (2,955/3,159). For the proposed FY 2022 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2022 occupational mix adjusted national average hourly wage is the following:

Proposed FY 2022 Occupational Mix Adjusted National Average Hourly Wage	$46.37

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2022 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2022, we are applying the occupational mix adjustment to 100 percent of the FY 2022 wage index. We calculated the occupational mix adjustment using data from the 2019 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The FY 2022 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$44.29
National LPN and Surgical Technician	$26.80
National Nurse Aide, Orderly, and Attendant	$18.49
National Medical Assistant	$19.52
National Nurse Category	$37.34

The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the

national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2019 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	42%
National Percentage of Hospital Employees in the All Other Occupations Category	58%
Range of Percentage of Hospital Employees in the Nurse Category (CBSA Level)	Low of 20 Percent in one CBSA to a high of 66 percent in another CBSA

We compared the proposed FY 2022 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. Applying the occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2022 Proposed Occupational Mix Adjusted Wage Indexes to the Proposed Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	226 (54.9%)
Number of Rural Areas Wage Index Increasing	27 (57.4%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	122 (29.6 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	2 (0.5 %)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	11 (23.4%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0 %)
Number of Urban Areas Wage Index Decreasing	185 (44.9 %)
Number of Rural Areas Wage Index Decreasing	20 (42.6 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	73 (17.7 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	2 (0.5 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8(17 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0 %)
Largest Positive Impact for an Urban Area	5.8 %
Largest Positive Impact for a Rural Area	4.3 %
Largest Negative Impact for an Urban Area	5.4 %
Largest Negative Impact for a Rural Area	2.5 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0

These results indicate that a smaller percentage of urban areas (54.9 percent) would benefit from the occupational mix adjustment than would rural areas (57.4 percent).

We also compared the FY 2022 wage data adjusted for occupational mix from the 2019 survey to the FY 2022 wage data adjusted for occupational mix from the 2016 survey. This analysis illustrates the effect on area wage indexes of using the 2019 survey data compared to the 2016 survey data; that is, it shows whether hospitals' wage indexes will increase or decrease under the 2019 survey data as compared to the prior 2016 survey data. Applying the occupational mix adjustment to the wage data, based on the 2019 survey, resulted in the following:

Comparison of the FY 2022 Proposed Occupational Mix Adjusted Wage Indexes: 2016 Survey to 2019 Survey	
Number of Urban Areas Wage Index Increasing	208 (50.5%)
Number of Rural Areas Wage Index Increasing	19 (40.4%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	121 (29.4 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	18 (4.4 %)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	9 (19.1%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	6 (6.4 %)
Number of Urban Areas Wage Index Decreasing	203 (49.3 %)
Number of Rural Areas Wage Index Decreasing	28 (59.6 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	110 (26.7 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	19 (4.6 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	19 (40.4 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	1 (2.1 %)
Largest Positive Impact for an Urban Area	14.9 %
Largest Positive Impact for a Rural Area	6.4 %
Largest Negative Impact for an Urban Area	10.7 %
Largest Negative Impact for a Rural Area	5.8 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	0
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0

These results indicate that the wage indexes of 49.3 percent of CBSAs overall will decrease due to application of the 2019 occupational mix survey data as compared to the 2016 occupational mix survey data. Further, a larger percentage of urban areas (50.5 percent) will benefit from the use of the 2019 occupational mix survey data as compared to the 2016 occupational mix survey data than will rural areas (40.4 percent).

G. Application of the Rural Floor, Application of the State Frontier Floor, Continuation of the Low Wage Index Hospital Policy, and Proposed Budget Neutrality Adjustment

1. Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). The rural floor for this FY 2022 proposed rule continues to be calculated without the wage data of hospitals that have reclassified as rural under § 412.103. We are not proposing any changes to the rural floor policy for FY 2022. Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, effective beginning in FY 2020, we remove the data of hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We are not proposing any changes to this policy for FY 2022.

Based on the FY 2022 wage index associated with this proposed rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 287 hospitals would receive an increase in their FY 2022 proposed wage index due to the application of the rural floor.

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have argued that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial

implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. (We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at 42 CFR 412.64(h)(4).) For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

In computing the imputed floor for an all-urban State under the original methodology established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever was higher was multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State.

We adopted a second, alternative methodology beginning in FY 2013 (77 FR 53368 through 53369) to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit another all-urban State, Rhode Island, which had only one CBSA. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. The lowest post-reclassified wage index assigned to a hospital in an all-urban State having a range of such values then was increased by this factor, the result of which established the State's alternative imputed floor. Under the updated OMB labor market area delineations adopted by CMS beginning in FY 2015, Delaware became an all-urban State, along with New Jersey and Rhode Island, and was subject to an imputed floor as well. In addition, we adopted a policy, as reflected at § 412.64(h)(4)(vi), that, for discharges on or after October 1, 2012, and before October 1, 2018, the minimum wage index value for a State is the higher of the value determined under the original methodology or the value determined under the alternative methodology. The regulations implementing the imputed floor wage index, both the original methodology and the alternative methodology, were set forth at § 412.64(h)(4).

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Thus, effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. As discussed previously, under § 412.64(h)(4)(vi), the minimum wage index value for hospitals in an all-urban State is the higher of the value determined using the original methodology (as set forth at § 412.64(h)(4)(i) through (v)) or the value determined using alternative methodology (as set forth at § 412.64(h)(4)(vi)(A) and (B)) for calculating an imputed floor. Therefore, as provided in § 412.64(h)(vi), we would apply the higher of the value determined under original or alternative methodology for calculating a minimum wage index, or imputed floor, for all-urban States effective beginning with FY 2022. We note that the rural floor values used in the alternative methodology at § 412.64(h)(4)(vi)(A) and (B) would not include the wage data of hospitals reclassified under § 412.103, because we currently calculate the rural floor without the wage data of such hospitals.

Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In other words, the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act, as amended, must be applied without taking into account the imputed floor adjustment under section 1886(d)(3)(E)(iv) of the Act. When the imputed floor was in effect from FY 2005 through FY 2018, to budget neutralize the increase in payments resulting from application of the imputed floor, we calculated the increase in payments resulting from the imputed floor together with the increase in payments resulting from the rural floor and applied an adjustment to reduce the wage index. By contrast, for FY 2022 and subsequent years, we are proposing to apply the imputed floor after the application of the rural floor and to apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor required under section 1886(d)(3)(E)(iv) of the Act.

We note, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022) into the calculation of the provider wage index for this proposed rule. We will include the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule. We note that CMS has posted, concurrent with the issuance of this proposed rule, estimated imputed floor values by state in a separate data file on the FY 2022 IPPS Proposed Rule web page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index,* and an aggregate payment impact for the imputed floor in the Appendix to this proposed rule.

The imputed floor under section 1886(d)(3)(E)(iv) of the Act applies to all-urban States, as defined in new subclause (IV). Section 1886(d)(3)(E)(iv)(IV) provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we believe it would be appropriate to consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

Therefore, under the definition at section 1886(d)(3)(E)(iv)(IV) of the Act, ''a State in which there are no hospitals classified as rural under this section'' would include a State that has a rural area but no hospitals that receive the rural area wage index under section 1886(d) of the Act. For purposes of this definition, hospitals redesignated as rural under section 1886(d)(8)(E) of the Act (412.103 rural reclassifications) would be considered classified as rural if they receive the rural wage index; however, hospitals that are deemed urban under section 1886(d)(8)(B) of the Act (in Lugar counties), or are reclassified to an urban area under section 1886(d)(10) of the Act (MGCRB reclassifications) would not be considered classified as rural because they do not receive the rural wage index. In contrast, we note that in the imputed floor policy in effect from FY 2005 through FY 2018, we did not consider a State to qualify for ''all urban status'' if there were one or more hospitals geographically located in the rural area of the State, even if all such hospitals subsequently reclassified to receive an urban area wage index. There is currently one State, Connecticut, that would be eligible for the imputed floor under this qualification in this proposed rule because there are currently no hospitals in Connecticut that are classified as rural under section 1886(d) for purposes of the wage index—in other words, there are no hospitals that receive the rural wage index value. There is one rural county in Connecticut. All hospitals in this county are either deemed urban under section 1886(d)(8)(B) of the Act or receive an MGCRB reclassification under section 1886(d)(10) of the Act. While several Connecticut hospitals were approved for rural reclassification under section 1886(d)(8)(E) of the Act, at this point in time, all have received a subsequent urban reclassification under section 1886(d)(10) of the Act.

Additionally, under section 1861(x) of the Act, the term State has the meaning given to it in section 210(h) of the Act. Because section 210(h) of the Act defines the word State to also include the District of Columbia and the Commonwealth of Puerto Rico, Washington, DC and Puerto Rico may also qualify as all-urban States for purposes of the imputed floor if the requirements of section 1886(d)(3)(E)(iv)(IV) of the Act are met. Based on data available for this proposed rule, the following States would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2022: New Jersey, Rhode Island, Delaware, Connecticut, and Washington, DC.

We are proposing to revise the regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) to implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. First, we propose to make the following revisions to the regulation text to specify that the imputed floor required under section 1886(d)(3)(E)(iv) of the Act would not be applied in a budget neutral manner:

- We are proposing to revise the introductory language at § 412.64(e)(4) to state that the budget neutrality adjustment for the imputed floor under paragraph (h)(4) applies only to discharges on or after October 1, 2004 and before October 1, 2018.
- We are proposing a conforming revision to § 412.64(e)(1)(ii) to refer to § 412.64(h)(4)(vii) (proposed in this proposed rule) in the introductory phrase that excepts certain provisions from the budget neutrality requirement specified in paragraph (e)(1)(ii).
- We are proposing to revise § 412.64(h)(4) to add a new clause (vii) stating that, for discharges on or after October 1, 2021, the minimum wage index computed under this paragraph may not be applied in a budget neutral manner.

In addition, we are proposing to revise the introductory language at § 412.64(h)(4) to specify that the minimum wage index and methodology described in that paragraph also apply for discharges on or after October 1, 2021. Further, we are proposing to revise § 412.64(h)(4)(vi) to specify that this clause also applies to discharges on or after October 1, 2021.

Finally, we are proposing to make the following revisions to § 412.64(h)(5). First, we are proposing to redesignate the current language at § 412.64(h)(5) as § 412.64(h)(5)(i) and to revise this language to reflect that it applies for purposes of applying the imputed floor for discharges on or after October 1, 2004 and before October 1, 2018. Second, we are proposing to add a new clause (ii) to § 412.64(h)(5) to reflect the proposed definition of all-urban State for purposes of applying the imputed floor for discharges on or after October 1, 2021, as previously discussed. Specifically, we are proposing at § 412.64(h)(5)(ii) that, for purposes of applying the imputed floor for discharges on or after October 1, 2021, an all-urban State is a State with no rural areas, as defined in § 412.64, or a State in which there are no hospitals classified as rural under section 1886 of the Act. We are further proposing at § 412.64(h)(5)(ii) that a hospital would be considered classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

3. State Frontier Floor for FY 2022

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In this FY 2022 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2022. In this proposed rule, 44 hospitals would receive the frontier floor value of 1.0000 for their FY 2022 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000.

The areas affected by the rural and frontier floor policies for the proposed FY 2022 wage index are identified in Table 2 associated with this proposed rule, which is available via the internet on the CMS website.

4. Continuation of the Low Wage Index Hospital Policy; Proposed Budget Neutrality Adjustment

To help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. We also provided for a transition in FY 2020 for hospitals experiencing significant decreases in their wage index values as compared to their final FY 2019 wage index, and made these changes in a budget neutral manner.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that

hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, the policy will continue in FY 2022. In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2022 and for subsequent fiscal years during which the low wage index hospital policy is in effect, we are proposing to apply a budget neutrality adjustment in the same manner as we applied it in FY 2021, as a uniform budget neutrality factor applied to the standardized amount. We refer readers to section II.A.4.b.of the addendum to this proposed rule for further discussion of the budget neutrality adjustment for FY 2022. For purposes of the low wage index hospital policy, based on the data for this proposed rule, the table below displays the 25th percentile wage index value across all hospitals for FY 2022.

FY 2022 Proposed 25th Percentile Wage Index Value	0.8418

H. Proposed FY 2022 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). In this FY 2022 IPPS/LTCH PPS proposed rule, as provided beginning with the FY 2021 IPPS/LTCH PPS final rule, we have included Table 4A which is titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the wage index tables for FY 2022.

I. Proposed Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). We note that this deadline was extended for applications for FY 2022 reclassifications to 15 days after the public display date of the FY 2021 IPPS/LTCH final rule at the Office of the Federal Register, using our authority under Section 1135(b)(5) the Act due to the COVID–19 Public Health Emergency. Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). We note that rural hospitals reclassifying under the MGCRB to another State's rural area are not eligible for the rural floor, because the rural floor may apply only to urban, not rural, hospitals.

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922

through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For a discussion on the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336).

We refer readers to the interim final rule with comment period (IFC) (CMS–1762–IFC) simultaneously submitted for public inspection with this proposed rule and published elsewhere in this issue of the **Federal Register** implementing the court's decision in *Bates Cnty. Mem'l Hosp.(''Bates'')* v. *Azar* for further changes to the treatment of § 412.103 hospitals reclassifying under the MGCRB.

2. MGCRB Reclassification and Redesignation Issues for FY 2022

a. FY 2022 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. At the time this proposed rule was drafted, the MGCRB had completed its review of FY 2022 reclassification requests. Based on such reviews, there are 496 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2022. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2022, hospitals reclassified beginning in FY 2020 or FY 2021 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 245 hospitals approved for wage index reclassifications in FY 2020 that will continue for FY 2022, and 317 hospitals approved for wage index reclassifications in FY 2021 that will continue for FY 2022. Of all the hospitals approved for reclassification for FY 2020, FY 2021, and FY 2022, based upon the review at the time of this proposed rule, 1,058 hospitals are in a MGCRB reclassification status for FY 2022 (with 161 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Finally, we note that in the FY 2021 IPPS/LTCH final rule (85 FR 58771–58778), CMS finalized an assignment policy for hospitals reclassified to CBSAs from which one or more counties moved to a new or different urban CBSA under the revised OMB delineations based on OMB Bulletin 18–04. We provided a table in that rule (85 FR 58777 and 58778) which described the assigned CBSA for all the MGCRB cases subject to this policy. For such reclassifications that continue to be active or are reinstated for FY 2022 (and FY 2023, if applicable), the CBSAs assigned in the FY 2021 IPPS/LTCH final rule continue to be in effect.

b. Proposed Revisions to the Regulations at § 412.278 for Administrator's Review

The regulation at § 412.278(b) addresses the procedure for a hospital's request for the Administrator's review of an MGCRB decision. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58788), we eliminated the prohibition on submitting a request by facsimile or other electronic means so that hospitals may also submit requests for Administrator review of MGCRB decisions electronically. In addition, we updated the regulation at § 412.278(b)(1) to require the hospital to submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group. We specified that copies to CMS' Hospital and Ambulatory Policy Group should be submitted via email to wage *index@cms.hhs.gov*. In this proposed rule, we are proposing to further revise the regulation at § 412.278(b)(1) to specify that the hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. We believe that this additional language would provide clarity and specificity by addressing any changes to the future technology platform for submission of the hospital's request for Administrator review. Hospitals will continue to be notified of the procedure for requesting Administrator review in the decision letters issued by the MGCRB.

The regulation at § 412.278(f)(2) addresses the timing for the Administrator's decision. Specifically, the Administrator issues a decision in writing to the party with a copy to CMS not later than 90 calendar days following the receipt of the party's request for review (§ 412.278(f)(2)(i)), or not later than 105 calendar days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator (§ 412.278(f)(2)(ii)). While the regulation at § 412.278(f)(2)(i) allows the Administrator to toll the 90 day timeframe for good cause, the regulation at § 412.278(f)(2)(ii) does not expressly provide for tolling the 105 day timeframe in the case of review at the discretion of the Administrator. We believe the policy regarding tolling should be the same regardless of whether the Administrator exercises review at the request of the hospital or at her discretion. Therefore, we are proposing to also provide for tolling of the 105 day timeframe at § 412.278(f)(2)(ii). Specifically, we are proposing to revise § 412.278(f)(2)(ii) to state that the Administrator issues a decision in writing to the party with a copy to CMS not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator, except the Administrator may, at his or her discretion, for good cause shown, toll such 105 days.

3. Redesignations Under Section 1886(d)(8)(B) of the Act (Lugar Status Determinations)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in

that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

J. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new outmigration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, most recently in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58787), we have applied the same policies, procedures, and computations since FY 2012. We are proposing to use them again for FY 2022, as we believe they continue to be appropriate. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2022, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2022, we are not proposing any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

Table 2 associated with this proposed rule (which is available via the internet on the CMS website) includes the proposed out-migration adjustments for the FY 2022 wage index. In addition, Table 4A associated with this proposed rule, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' (also available via the internet on the CMS website) consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2022 identified by FIPS county code, the proposed FY 2022 out-migration adjustment, and the number of years the adjustment will be in effect.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

1. Application for Rural Status and Lock-In Date

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may

apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for a discussion on our current policy to calculate the rural floor without the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103.

Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) that we believed there should be a definitive timeframe within which a hospital must apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates. Therefore, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (6) to add a lock-in date by which a hospital's application for rural status must be filed in order to be treated as rural in the wage index and budget neutrality calculations for payment rates for the next Federal fiscal year. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41384 through 41386), we changed the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline, the usual public comment deadline for the IPPS proposed rule. We revised § 412.103(b)(6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

The lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41385 through 41386), this lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims will be paid reflecting its rural status beginning on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

2. Proposed Changes to Cancellation Requirements at § 412.103(g)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42322), we noted that if an application is approved by the CMS Regional Office after our ratesetting lock-in date, the final rule rural wage index value would most likely not include the data for this hospital in the ratesetting calculation. Therefore, we noted that this may incentivize relatively low wage index hospitals to time their applications to avoid reducing the State's rural wage index. These hospitals could then conceivably cancel their rural reclassifications (effective for next FY), and then reapply again after the 'lock-in date.' We stated in the FY 2020 IPPS/LTCH PPS final rule that we planned to monitor this situation over the course of FY 2020, and determine if it is necessary to take action to prevent this type of gaming in future rulemaking.

We stated in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58788) that hospitals in certain states were indeed timing their rural reclassifications and applications to exploit the rural reclassification process in order to obtain higher wage index values. For example, for FY 2020, at least twenty-one hospitals in one State obtained § 412.103 rural reclassifications after the FY 2020 lock-in date, effectively receiving their State's rural wage index without having their wage data included, which would have lowered their State's rural wage index. These hospitals then requested to cancel their § 412.103 rural reclassifications effective for FY 2021, in accordance with § 412.103(g)(3). Similarly, five hospitals in another State, hospitals with wage data that would have lowered their State's FY 2021 rural wage index, requested to cancel their § 412.103 rural reclassifications for FY 2021, so that the rural wage index would be set using the data of one geographically rural hospital and two hospitals reclassified under § 412.103 that withdrew their MGCRB reclassifications for FY 2021. All five of these hospitals that withdrew their rural reclassification effective October 1, 2021 have since reapplied and been approved for rural reclassification. At least a dozen additional hospitals in this State were also approved for rural reclassification during FY 2021. By timing their applications to be approved after the lock-in date, these hospitals are receiving a higher rural wage index without having their own data included in the rural wage index calculation. We believe this practice of applying for and canceling rural reclassification to manipulate a State's rural wage index is detrimental to the stability and the accuracy of the Medicare wage index system.

In the FY 2008 IPPS/LTCH final rule (72 FR 47371 through 47373), CMS addressed an issue of hospitals applying for rural reclassification and then requesting cancelation soon after approval. Certain hospitals were using rural reclassifications to obtain RRC status, then canceling their rural reclassification so they could obtain an MGCRB reclassification, and using their prior RRC status in order to benefit from favorable MGCRB reclassification rules. To address this, CMS finalized a policy that required such hospitals to maintain rural status for one full cost reporting year before their rural reclassification could be canceled (cancelation was not effective until the hospital had been paid as rural for at least one 12-month cost-reporting period, and not until the beginning of the FY following the request for cancelation and the 12-month cost reporting period (§ 412.103(g)(2)(ii)). As discussed in the FY 2008 IPPS/LTCH proposed rule (72 FR 24812), we stated that we believed this policy was reasonable, given that acquired rural status for IPPS hospitals should be a considered decision for hospitals that truly wish to be considered as rural, and not purely as a mechanism for reclassifying. In the April 21, 2016 interim final rule with comment period (81 FR 23428 through 23438)), CMS implemented provisions amending our regulations to allow

hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. In the FY 2020 IPPS/LTCH final rule (42320 through 42321), CMS removed the requirement that RRCs must be paid as rural for one cost reporting year before canceling rural reclassification, as there no longer was an incentive to obtain and then cancel rural reclassification status to obtain an MGCRB reclassification. However, given our observations over the past two fiscal years of a new form of wage index gaming, as described in the previous paragraph, we believe it is necessary and appropriate to adopt a similar measure to prevent rural reclassifications from being used purely as a mechanism for statewide wage index manipulation.

Specifically, we are proposing that requests to cancel rural reclassifications must be submitted to the CMS Regional Office not earlier than one calendar year after the reclassification effective date. For example, a hospital that was approved to receive a rural reclassification effective October 1, 2021 would not be eligible to request cancelation until October 1, 2022. We are also proposing an additional modification to the effective date of these cancelation requests. Currently, all rural reclassification requests must be submitted not less than 120 days before the end of a fiscal year (that is, assuming the fiscal year ends on September 30th, no cancellation requests may be submitted after June 2nd and before October 1st). This timeframe typically aligns closely with the rural reclassification lock-in date under § 412.103(b)(6) (the hospital's rural reclassification application must be approved by the CMS Regional Office no later than 60 days after the public display date of the IPPS/LTCH PPS proposed rule at the Office of the Federal Register in order for a hospital to be treated as rural in the wage index and budget neutrality calculations for the next Federal fiscal year). The lock-in date and the 120 day cancelation deadline provide timeframes within which a hospital must be approved for rural reclassification (to have its rural status included in the wage index and budget neutrality calculations for the next fiscal year) or request cancelation of rural status, respectively, and also give CMS adequate time to incorporate these changes in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for payment rates for the next Federal fiscal year. Rural reclassifications are effective as of the date the application is received (§ 412.103(b)(5), (d)), and CMS Regional Offices are required to render a determination within 60 days of receipt of the application (§ 412.103(c)). We believe that even with the proposed one-year minimum reclassification period before cancelation can be requested, there still would be a possibility that hospitals could time their applications around the lock-in date and 120 day deadline to continue to manipulate the State's rural wage index calculation. For example, assuming the lock-in date for a given year was May 30th (that is, the date by which the Regional Office must approve the application in order for the rural reclassification to be included in the wage index and budget neutrality calculations for the upcoming fiscal year), a hospital may choose to apply for rural reclassification on May 25th, virtually assuring that it could not be approved in time to be considered for wage index development purposes for the upcoming fiscal year. Assuming our one-year minimum reclassification period proposal is finalized, the hospital could request cancelation on May 25th the following year. Since that date would be prior to 120 day cancelation deadline, a hospital could once again cancel its rural reclassification, then reapply for rural reclassification status, and once again receive the rural wage index for the upcoming fiscal year while excluding its own wage data from the calculation. To address this rural wage index manipulation, we are proposing to eliminate the current rule at § 412.103(g)(3) (that cancelation must be requested 120 days prior to the end of the fiscal year and is effective beginning with the next fiscal year) and replace it with a policy that ensures that a hospital approved for rural reclassification (and that does not receive an additional reclassification) would have its data included in the calculation of the rural wage index for at least one Federal fiscal year before the rural reclassification status could be canceled. Specifically, we are proposing to make cancellation requests effective for the Federal fiscal year that begins in the calendar year after the calendar year in which the cancelation request is submitted. For example, we are proposing that a cancelation request submitted on December 31, 2021 would be effective October 1, 2022. But a cancellation request submitted one day later on January 1, 2022 would not become effective until October 1, 2023.

Specifically, we are proposing to add 412.103(g)(4) to state that for all written requests submitted by hospitals on or after October, 1, 2021 to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification. The hospital's cancellation of its rural reclassification would be effective beginning the Federal fiscal year that begins in the calendar year following the calendar year in which the cancelation request is submitted. We are also proposing to make conforming revisions to § 412.103(g)(3) to reflect that the rule in § 412.103(g)(3) applies to requests for cancelation of rural reclassification submitted on or after October 1, 2019 and before October 1, 2021.

We considered an alternative policy to increase the current 120 day cancelation deadline to a sufficient number of days to ensure that hospitals could not time applications and cancelations to straddle the lock-in date. Given the floating nature of the lock-in date due to the publication of the proposed rule varying year to year, it is difficult to determine how long that period would need to be in order to ensure our policy goals of preventing rural wage index manipulation are met. We acknowledge that our proposals would increase the amount of time a hospital must retain rural reclassification before it could cancel that status. However, we do not believe these proposed changes would have an undue impact on hospitals. In the FY 2021 final rule, 81 percent of hospitals with rural reclassifications were assigned a wage index based on an MGCRB or ''Lugar'' reclassification, and would not receive a wage index based on their rural reclassification.[933] Another 11 percent received a rural wage index value that was greater than or equal to their geographically urban area. Since these hospitals are typically benefiting by maintaining rural reclassification status, we do not believe they would be negatively affected by our proposals. More than half of the remaining 9 percent of hospitals with rural reclassifications do so to maintain MDH or SCH status. These special statuses convey additional financial benefits to hospitals and are not typically or routinely canceled by hospitals. We note that in the FY 2008 IPPS/LTCH final rule (72 FR 47372), we addressed a comment that expressed concern that the proposed requirement that a hospital must maintain rural status for at least a full 12 months could adversely affect hospitals with SCH

[933] ''Lugar'' hospitals may reclassify as rural and retain the urban wage index deemed under section 1886(d)(8)(B) of the Act, as discussed in the FY 2017 IPPS/LTCH final rule (81 FR 56929).

status since the payment rate as a rural SCH may be only slightly higher than the urban Federal rate. Since the form of wage index manipulation addressed by the proposed policy in FY 2008 specifically involved hospitals acquiring rural status to become RRCs, CMS opted to limit the policy finalized in FY 2008 to RRCs only. By contrast, the form of wage index manipulation we are addressing in this proposed rule is not limited to any specific hospital type. Therefore, we believe it is appropriate to apply it to all hospitals with rural reclassification status. We believe the proposed policy of requiring that rural reclassification be in effect for at least one year before cancelation can be requested, and the proposed policy to make rural reclassification cancelations effective beginning the Federal fiscal year that begins in the calendar year after the calendar year in which the cancelation request is submitted would reduce the instances of wage index manipulation described previously, as well as reduce volatility and promote accuracy in overall wage index values by ensuring that hospitals that are being paid a State's rural wage index are eventually included, when applicable, in that rural wage index calculation. We note that this form of manipulation (hospitals canceling rural status to remove their wage data from the rural wage index calculation) resulted in the rural wage index for one state increasing by over 4 percent between the FY 2020 proposed rule and the FY 2020 final rule. Based on our analysis, that figure could have been significantly greater (as high as 10 percent) in certain States. We further believe these proposed policies provide adequate time for hospitals to review their reclassification status and make appropriate decisions for future fiscal years. Hospitals that meet the proposed one-year minimum requirement in proposed § 412.103(g)(4) would have opportunity between the publication date of the final rule (and potential correction notices) and the end of the calendar year to evaluate whether to cancel or maintain their rural status for the next fiscal year.

3. Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board Interim Final Rule (CMS–1762–IFC) to implement *Bates Co.* v. *Azar* Adverse Court Decision

In the interim final rule with comment period (IFC) (CMS–1762–IFC) simultaneously submitted for public inspection with this proposed rule and publishing elsewhere in this issue of the **Federal Register**, CMS made regulatory changes in order to align our policy with the decision in *Bates County Memorial Hospital* v. *Azar,* 464 F. Supp. 3d 43 (D.D.C. 2020). Specifically, the IFC revised the regulations at § 412.230 to allow hospitals with a rural redesignation under Section 1886(d)(8)(E) to reclassify under the MGCRB using the rural reclassified area as the geographic area in which the hospital is located effective with reclassifications beginning with fiscal year (FY) 2023. We would also apply the policy in the IFC when deciding timely appeals before the Administrator of applications for reclassifications beginning with FY 2022 that were denied by the MGCRB due to the policy in effect prior to the IFC, which did not permit hospitals with rural redesignations to use the rural area's wage data for purposes of reclassifying under the MGCRB.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2022 wage index were made available on May 18, 2020 and the preliminary CY 2019 occupational mix data files for the proposed FY 2022 wage index were made available on September 8, 2020 through the internet on the CMS website at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page*.

On January 29, 2021, we posted a public use file (PUF) at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page* containing FY 2022 wage index data available as of January 28, 2021. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2017 through September 30, 2018; that is, FY 2018 wage data), a tab with the occupational mix data (which includes data from the CY 2019 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 29, 2021 wage data PUF, and a tab containing the CY 2019 occupational mix data of the hospitals deleted from the January 29, 2021 occupational mix PUF. In a memorandum dated January 22, 2021, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 29, 2021 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2022 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at: *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums*.

In a memorandum dated April 14, 2020, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files posted on May 18, 2020, the requirement to submit the new CY 2019 occupational mix surveys by August 3, 2020 and the process and timeframe for requesting revisions. Subsequently, in a memorandum dated July 31, 2020, we revised the date hospitals were required to submit the new CY 2019 occupational mix surveys from August 3, 2020 to September 3, 2020, the date the preliminary CY 2019 occupational mix survey data files were scheduled to be posted from August 6, 2020 to September 8, 2020 and the timeframe for requesting revisions to the new CY 2019 occupational mix survey data.

If a hospital wished to request a change to its data as shown in the May 18, 2020 preliminary wage data files (or September 8, 2020 preliminary CY 2019 occupational mix survey data files), the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 3, 2020 (or by September 10, 2020 for preliminary CY 2019 occupational mix survey data files). Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. November 16, 2020 was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 5, 2020 was the date by when MACs notified State hospital

associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2021. CMS published the wage index PUFs that included hospitals' revised wage index data on January 29, 2021. Hospitals had until February 16, 2021, to submit requests to the MACs to correct errors in the January 29, 2021 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 29, 2021 PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 16, 2021 for the FY 2021 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 19, 2021. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 2, 2021. Data that were incorrect in the preliminary or January 29, 2021 wage index data PUFs, but for which no correction request was received by the February 16, 2021 deadline, are not considered for correction at this stage. In addition, April 2, 2021 was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 29, 2021 PUF and at least 14 calendar days prior to April 2, 2021 (that is, March 19, 2021), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 2, 2021 for the FY 2022 wage index). We refer readers to the wage index timeline for complete details.

Hospitals are given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2022-ipps-proposed-rule-home-page*. Table 2 associated with the proposed rule contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2022 wage index which was constructed from FY 2018 data.. We note that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2021.

We plan to post the final wage index data PUFs in late April 2021 on the CMS website at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2022-wage-index-home-page*. The April 2021 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 19, 2021, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2021 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 19, 2021.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 29, 2021 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2021 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC so that it is received no later than May 28, 2021. May 28, 2021 is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 2, 2021 (that is, March 20, 2021), and at least 14 calendar days prior to May 28, 2021 (that is, May 14, 2021), that do not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 28, 2021 (that is, May 15, 2021) may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2022 wage index timeline posted on the CMS website at: *https://www.cms.gov/files/document/fy-2022-hospital-wage-index-development-time-table.pdf*, the May appeals are required to be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely (that is, by May 28, 2021) by CMS and the MACs will be incorporated into the final FY 2022 wage index, which will be effective October 1, 2021.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2022 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2021, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2022 wage index by August 2021, and the implementation of the FY 2022 wage index on October 1, 2021. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 28, 2021, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 28, 2021 for the FY 2022 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 28, 2021 deadline for the FY 2022 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 28, 2021 deadline for the FY 2022 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 29 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.L.1. of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 29 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed

in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 29 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 29 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2022 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Proposed Labor-Related Share for the FY 2022 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we rebased and revised the hospital market basket. We established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, we finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. In addition, in FY 2018, we implemented this revised and rebased labor-related share in a budget neutral manner (82 FR 38522). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58793), for FY 2021, we continued to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2020.

As described in section IV. of the preamble of this proposed rule, effective beginning FY 2022, we are proposing to rebase and revise the IPPS market basket to reflect a 2018 base year. We also are proposing to recalculate the labor-related share for discharges occurring on or after October 1, 2021 using the proposed 2018-based IPPS market basket. As discussed in Appendix A of this proposed rule, we are proposing this rebased and revised labor -related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we would not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. As described in section IV. of the preamble of this proposed rule, beginning with FY 2022, we are proposing to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the proposed 2018-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other Labor-Related Services, as measured in the proposed 2018-based IPPS market basket. Therefore, for FY 2022, we are proposing to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021.

As discussed in section V.B. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application

to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2022, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2022 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2022, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2022, we are proposing to apply the wage index to the proposed labor-related share of 67.6 percent of the national standardized amount.

IV. Proposed Rebasing and Revising of the Hospital Market Baskets for Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to provide inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to provide hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. An explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). We also refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175) in which we discussed the most recent previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2018 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, and the proportion of total costs that each category represents are calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

We last rebased the hospital market basket cost weights effective for FY 2018 (82 FR 38158 through 38175), with 2014 data used as the base period for the construction of the market basket cost weights. For this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to rebase the IPPS operating market basket to reflect the 2018 cost structure for IPPS hospitals and to revise applicable cost categories and price proxies used to determine the IPPS market basket, as discussed in this rule. We are also proposing to rebase and revise the Capital Input Price Index (CIPI) as described in section IV.D. of the preamble of this proposed rule.

B. Rebasing and Revising the IPPS Market Basket

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. ''Rebasing'' means moving the base year for the structure of costs of an input price index (for example, in this proposed rule, we are proposing to shift the base year cost structure for the IPPS hospital index from 2014 to 2018). ''Revising'' means changing data sources or price proxies used in the input price index. As published in the FY 2006 IPPS final rule (70 FR 47387), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket. We established a rebasing frequency of every 4 years and, therefore, for the FY 2022 IPPS update, we are proposing to rebase and revise the IPPS market basket from 2014 to 2018. We are inviting public comments on our proposed methodology.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data

The major source of expenditure data for developing the proposed rebased and revised hospital market basket cost weights is the 2018 Medicare cost reports. These 2018 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2017

and before October 1, 2018. We are proposing to use 2018 as the base year because we believe that the 2018 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for IPPS hospitals at the time of rulemaking. We believe it is important to regularly rebase and revise the IPPS market basket to reflect more recent data. Historically, the cost weights change minimally from year to year as they represent percent of total operating costs rather than cost levels; however, given the COVID–19 public health emergency we will continue to monitor the upcoming Medicare cost report data to see if a more frequent rebasing schedule is necessary than our current schedule of every 4 years. As was done in previous rebasings, these cost reports are from IPPS hospitals only (hospitals excluded from the IPPS and CAHs are not included) and are based on IPPS Medicare-allowable operating costs. IPPS Medicare-allowable operating costs are costs that are eligible to be paid under the IPPS. For example, the IPPS market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS and, therefore, these costs are not IPPS Medicare-allowable costs.

The current set of instructions for the Medicare cost reports for hospitals (Form 2552–10, OMB Control Number 0938–0050) can be found in Chapter 40 at the following website (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*, accessed February 17, 2021). As described in these instructions, effective for cost reporting periods beginning on or after October 1, 2015, Worksheet S–3, Part II was revised to add lines 14.01, 14.02, 25.50, 25.51, 25.52, and 25.53, to enhance the wage index data collection. This modification was made for Transmittal 10 and is specifically highlighted in the instructions, which can be found at the following website: (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R10P240.pdf*, accessed February 17, 2021). Therefore, as noted later in this section, for the 2018-based IPPS market basket, we are proposing to use these more detailed lines for the development of the market basket cost categories. These detailed lines were not available at the time we finalized the 2014-based IPPS market basket.

We are proposing to derive costs for eight major expenditures or cost categories for the 2018-based IPPS market basket from the CMS Medicare cost reports (Form 2552–10, OMB Control Number 0938–0050): Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (Malpractice), Blood and Blood Products, Home Office/Related Organization Contract Labor, and a residual ''All Other'' category. The residual ''All Other'' category reflects all remaining costs that are not captured in the other seven cost categories. These are the same major cost categories from the Medicare cost reports that were derived for the 2014-based IPPS market basket. In this rule, we describe the detailed methodology for obtaining costs for each of the seven cost categories directly determined from the Medicare cost reports.

In order to create a market basket that is representative of IPPS hospitals serving Medicare patients and to help ensure accurate major cost weights (which is the percent of total Medicare-allowable operating costs, as defined in this rule), we propose to apply edits to remove reporting errors and outliers. Specifically, the IPPS Medicare cost reports used to calculate the market basket cost weights exclude any providers that reported costs less than or equal to zero for the following categories: Total Medicare inpatient costs (Worksheet D, Part I, column 1, line 49); Medicare PPS payments (Worksheet E, Part A, column 1, line 59); Total salary costs (Worksheet S–3, Part II, column 2, line 1). We also limited our sample to providers that had a Medicare cost reporting period that was between 10 and 14 months. The final sample used included roughly 3,200 Medicare cost reports (about 94 percent of the universe of IPPS Medicare cost reports for 2018). The sample of providers is representative of the national universe of providers by ownership-type (proprietary, nonprofit, and government) and by urban/rural status.

First, we are proposing to calculate total Medicare-allowable operating costs for each hospital. We are proposing that total Medicare-allowable operating costs are equal to noncapital costs (Worksheet B, Part I, column 26 less Worksheet B, Part II, column 26) that are attributable to the Medicare-allowable cost centers of the hospital. We are proposing that Medicare-allowable cost centers are lines 30 through 35, 50 through 60, 62 through 76, 90, 91, 92.01, 93, 96 and 97. This is the same general methodology that was used for the 2014-based IPPS market basket. However, we note that for the development of the 2018-based IPPS market basket, we conducted a detailed review of the cost centers and are now proposing to include lines 52, 96, and 97 when deriving total Medicare-allowable operating costs as these reflect Medicare-allowable services that are reimbursed under the IPPS.

(1) Wages and Salaries Costs

To derive wages and salaries costs for the Medicare-allowable cost centers, we are proposing to first calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, Part II, column 4, line 1. We are then proposing to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas) as well as a portion of overhead wages and salaries attributable to these excluded areas. This is the same general methodology that was used to derive wages and salaries costs for the 2014-based IPPS market basket. However, we note that we are proposing minor changes to the Medicare cost report lines that are used to derive excluded area wages and salaries as well as overhead wages and salaries attributable to these areas as described in this rule as we believe these represent a technical improvement to the Medicare cost report lines used for the 2014-based IPPS market basket. The description of the detailed methodology used for the 2014-based IPPS market basket was provided in the FY 2018 IPPS/LTCH final rule (82 FR 38159).

Specifically, we are proposing to calculate excluded area wages and salaries as equal to the sum of Worksheet S–3, Part II, column 4, lines 3, 4.01, 5, 6, 7, 7.01, 8, 9, and 10 less Worksheet A, column 1, lines 20 and 23. Overhead wages and salaries are attributable to the entire IPPS facility. Therefore, we are proposing to only include the proportion attributable to the Medicare-allowable cost centers. Specifically, we are proposing to estimate the proportion of overhead wages and salaries that are not attributable to Medicare-allowable costs centers (that is, excluded areas) by first calculating the ratio of total Medicare-allowable operating costs as previously defined to total facility operating costs (Worksheet B, Part I, column 26, line 202 less Worksheet B, Part I, column 0, lines 1 and 2). We then are proposing to multiply this ratio by total overhead wages and salaries (Worksheet S–3, Part II, column 4, lines 26, 27, 29 through 32, 34, and 36 through 43).

Therefore, the proposed wages and salaries costs are equal to total wages and salaries costs less: (a) Excluded area wages and salaries costs and b) overhead wages and salaries costs attributable to the excluded areas.

(2) Employee Benefits Costs

We are proposing to derive employee benefits costs using a similar methodology as the wages and salaries costs; that is, reflecting employee benefits costs attributable to the Medicare-allowable cost centers. First, we calculate total unadjusted employee benefits costs as the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 20, 22, and 25.52. The 2014-based IPPS market basket used Worksheet S–3, Part II, column 4, lines 17, 18, 20 and 22 to derive the costs for this category. As described previously, line 25.52 reflects a newly added line to Worksheet S–3, Part II since the development of the 2014-based IPPS market basket.

We then exclude those employee benefits attributable to the overhead wages and salaries for the non-Medicare-allowable cost centers (that is, the excluded areas). Employee benefits attributable to the non-Medicare-allowable cost centers are derived by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) by excluded overhead wages and salaries (as previously described in section IV.B.1.a.(1). of the preamble of this proposed rule for wages and salaries costs). A similar methodology was used in the 2014-based IPPS market basket.

(3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described in this rule. We are proposing to derive contract labor costs for the 2018-based IPPS market basket as the sum of Worksheet S–3, Part II, column 4, lines 11, 13, and 15. A similar methodology was used in the 2014-based IPPS market basket.

(4) Professional Liability Insurance Costs

We are proposing that professional liability insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses, and self-insurance costs reported on Worksheet S–2, Part I, columns 1 through 3, line 118.01. A similar methodology was used for the 2014-based IPPS market basket.

(5) Pharmaceuticals Costs

We are proposing to calculate pharmaceuticals costs as total costs reported for the Pharmacy cost center (Worksheet B, Part I, column 0, line 15) and Drugs Charged to Patients cost center (Worksheet B, Part I, column 0, line 73) less wages and salaries attributable to these two cost centers (Worksheet S–3, Part II, column 4, line 40 and Worksheet A, column 1, line 73) less estimated employee benefits attributable to these two cost centers. We are proposing to estimate the employee benefits costs by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) by total wages and salaries costs for the Pharmacy and Drugs Charged to Patients cost centers (equal to the sum of Worksheet S–3, Part II, column 4, line 40 and Worksheet A, column 1, line 73). The same general methodology was used for the 2014-based IPPS market basket. However, we note that for the 2014-based IPPS market basket, for calculating the total nonsalary costs we used Worksheet A, column 2 for each cost center instead of our proposed method of using Worksheet B, Part I, column 0, less salary costs. We are proposing to use Worksheet B, Part I, column 0 as this would reflect reclassifications and adjustments (which are made on columns subsequent to Worksheet A columns 1 and 2).

(6) Blood and Blood Products Costs

We are proposing to calculate blood and blood products costs as total costs reported for the Whole Blood & Packed Red Blood Cells cost center (Worksheet B, Part I, column 0, line 62) and the Blood Storing, Processing, & Transfusing cost center (Worksheet B, Part I, column 0, Line 63) less wages and salaries attributable to these two cost centers (Worksheet A, column 1, lines 62 and 63) less estimated employee benefits attributable to these two cost centers. We estimate these employee benefits costs by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) by total wages and salaries for the Whole Blood & Packed Red Blood Cells and Blood Storing, Processing, & Transfusing cost centers (equal to the sum of Worksheet A, Column 1, lines 62 and 63). The same general methodology was used for the 2014-based IPPS market basket. However, we note that for the 2014-based IPPS market basket, for calculating the total nonsalary costs we used Worksheet A, column 2 for lines 62 and 63 instead of our proposed method of using Worksheet B, Part I, column 0, lines 62 and 63, less salary costs. Similar to our proposed method for Pharmaceuticals costs, we are proposing to use Worksheet B, Part I, column 0 as this would reflect reclassifications and adjustments (which are made on columns subsequent to Worksheet A columns 1 and 2).

(7) Home Office Contract Labor/Related Organization Costs

We are proposing to determine home office/related organization contract labor costs using data reported on Worksheet S–3, Part II, column 4, lines 14.01, 14.02, 25.50, and 25.51. Home office/related organization contract labor costs in the 2014-based IPPS market basket were calculated using a similar method except we used data reported on Worksheet S–3, Part II, column 4, line 14. As described previously, effective for cost reporting periods beginning on or after October 1, 2015 (Transmittal 10), Worksheet S–3, Part II was revised to add lines 14.01, 14.02, 25.50, 25.51, 25.52, and 25.53, to enhance the wage index data collection. Therefore, for the 2018-based IPPS market basket, we are proposing to use these more detailed lines; however, the expenses captured on these lines would be similar to the expenses originally reported on line 14, prior to the break out of the expenses on these new more detailed lines.

In addition, for the 2014-based IPPS market basket, we then multiplied the home office/related organization contract labor costs by the ratio of total Medicare-allowable operating costs to total operating costs. However, for the 2018-based IPPS market basket, we are no longer proposing to apply this adjustment since the Medicare cost report instructions effective for Transmittal 10 now state that the costs reported on these lines should reflect costs associated with Medicare-allowable cost centers. Therefore, we no longer believe this adjustment is necessary.

b. Final Major Cost Category Computation

After we derived costs for the seven major cost categories for each provider using the Medicare cost report data as previously described, we are proposing to address data outliers using the following steps. First, we divide the costs for each of the seven categories (calculated as previously described in this section) by total Medicare-allowable operating costs for the provider

(calculated as previously described in this section) to obtain cost weights for each PPS hospital.

For each of the major cost weights except the Home Office/Related Organization Contract Labor cost weight, we are proposing to trim the data to remove outliers (a standard statistical process) by: (1) Requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable operating costs be greater than zero; and (2) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable operating costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2014-based IPPS market basket. After the outliers have been removed, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare-allowable operating costs across all remaining providers to obtain a cost weight for the proposed 2018-based IPPS market basket for the given category.

For the Home Office/Related Organization Contract Labor cost weight, we are proposing to apply a trim that excludes those reporters above the 99th percentile. This allows all providers' Medicare-allowable costs to be included, even if their home office/related organization contract labor costs were reported to be zero. The Medicare cost report data (Worksheet S–2, Part I, line 140) indicate that not all hospitals have a home office. IPPS hospitals without a home office would report administrative costs that might typically be associated with a home office in the Wages and Salaries and Employee Benefits cost weights, or in the residual ''All Other'' cost weight if they purchased these types of services from external contractors. We believe the trimming methodology that excludes those who report a Home Office/Related Organization Contract Labor cost weight above the 99th percentile is appropriate as it removes extreme outliers while also allowing providers with zero home office/related organization contract labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation. Next, similar to the other cost weights, after the outliers have been removed, we sum the costs across all remaining providers. We then divide this by the sum of total Medicare-allowable operating costs across all remaining providers to obtain a cost weight for the proposed 2018-based IPPS market basket.

The trimming process is done individually for each cost category so that providers excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these proposed trimming methods are the same types of edits performed for the 2014-based IPPS market basket, as well as other PPS market baskets (including but not limited to SNF market basket and HHA market basket). We believe this trimming process improves the accuracy of the data used to compute the major cost weights by removing possible misreported data. We note that for each of the cost weights we evaluated the distribution of providers and costs by ownership-type, and by urban/rural status. For all of the cost weights, the trimmed sample was nationally representative.

Finally, we calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. Table IV–01 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for this proposed rule.

TABLE IV-01.—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major Cost Categories	2014-based IPPS Market Basket	Proposed 2018-based IPPS Market Basket
Wages and Salaries	42.1	39.7
Employee Benefits	12.0	11.3
Contract Labor	1.8	2.0
Professional Liability Insurance (Malpractice)	1.2	1.0
Pharmaceuticals	5.9	7.1
Blood and Blood Products	0.8	0.6
Home Office/Related Organization Contract Labor	4.2	5.9
"All Other" Residual	32.0	32.4

From 2014 to 2018, the Wages and Salaries and Employee Benefits cost weights as calculated directly from the Medicare cost reports decreased by approximately 2.4 percentage points and 0.7 percentage point, respectively, while the Contract Labor cost weight increased slightly by 0.2 percentage point.

As we did for the 2014-based IPPS market basket (82 FR 38162), we are proposing to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2018 Medicare cost report data, this percentage is 78 percent. Therefore, we are proposing to allocate approximately 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 22 percent to the Employee Benefits cost weight. The 2014-based IPPS market basket also allocated 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight.

Table IV–02 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the 2014-based IPPS market basket and the proposed 2018-based IPPS market basket. In aggregate, the

Compensation cost weight (calculated using more detailed decimal places) decreased from 55.8 percent to 53.0 percent, or 2.8 percentage points.

TABLE IV-02.—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major Cost Categories	2014-Based IPPS Market Basket	Proposed 2018-Based IPPS Market Basket
Total Compensation	**55.8**	**53.0**
Wages and Salaries	43.4	41.2
Employee Benefits	12.4	11.7

*Totals may not sum due to rounding

c. Derivation of the Detailed Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2018 Medicare cost report data into more detailed cost categories, we are proposing to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the BEA. These data are publicly available at the following website: *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years on a lagged basis, with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[934] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we are proposing to inflate the detailed 2012 Benchmark I–O data forward to 2018 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. In our calculations for this proposed rule, we repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2018. These resulting 2018 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2018-based IPPS market basket. For example, the cost for Food: Direct Purchases represents 4.8 percent of the sum of the ''All Other'' 2012 Benchmark I–O Hospital Expenditures inflated to 2018. Therefore, the Food: Direct Purchases cost weight represents 4.8 percent of the proposed 2018-based IPPS market basket's ''All Other'' cost category (32.4 percent), yielding a Food: Direct Purchases proposed cost weight of 1.6 percent in the proposed 2018-based IPPS market basket (0.048 × 32.4 percent = 1.6 percent). For the 2014-based IPPS market basket (82 FR 38162), we used the same methodology utilizing the 2007 Benchmark I–O data (aged to 2014).

Using this methodology, we are proposing to derive 17 detailed cost categories from the proposed 2018-based IPPS market basket residual cost weight (32.4 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity and Other Non-Fuel Utilities; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10) Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12) Installation, Maintenance, and Repair Services; (13) All Other: Labor-Related Services; (14) Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17) All Other: Nonlabor-Related Services.

The 2014-based IPPS market basket had a separate cost category for Water and Sewerage. Due to the size of the estimated cost weight (approximately 0.1 percent), we are proposing that these costs be included in the Electricity and Other Non-Fuel Utilities cost category.

2. Selection of Proposed Price Proxies

After computing the proposed 2018 cost weights for the IPPS market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the proxy for professional liability insurance (PLI), all the proxies we are proposing are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- Producer Price Indexes—Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- Consumer Price Indexes—Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.
- Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- Reliability. Reliability indicates that the index is based on valid statistical

[934] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

- Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market basket levels are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

In this rule, we present a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing to use for the proposed 2018-based IPPS market basket are the same as those used for the 2014-based IPPS market basket.

(1) Wages and Salaries

We are proposing to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU10262200000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(2) Employee Benefits

We are proposing to use the ECI for Total Benefits for All Civilian Workers in Hospitals to measure the price growth of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2014-based IPPS market basket.

(3) Fuel: Oil and Gas

Similar to the 2014-based IPPS market basket, we are proposing to use a blend of the PPI Industry for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark I–O data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that approximately 96 percent of hospital Fuel: Oil, and Gas expenses are for Petroleum Refineries (NAICS 324110) and Natural Gas (NAICS 221200) expenses, with Petroleum Refineries expenses accounting for approximately 90 percent and Natural Gas expenses accounting for approximately 10 percent of this sum. We are proposing to create blended index of these expenses based on each NAICS' expenses as share of their sum. Therefore, we are proposing to use a blend of 90 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2014-based IPPS market basket used a 70/30 blend of these price proxies, reflecting the 2007 I–O data (82 FR 38163). We believe that these two price proxies continue to be the most technically appropriate indices available to measure the price growth of the Fuel: Oil, and Gas cost category in the proposed 2018-based IPPS market basket.

(4) Electricity and Other Non-Fuel Utilities

We are proposing to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category, as Electricity costs account for 93 percent of these expenses. This is the same price proxy used for the Electricity cost category in the 2014-based IPPS market basket. As previously noted, we are proposing to include Water and Sewerage costs within the Electricity and Other Non-Fuel Utilities cost category, and to no longer use the CPI for Water and Sewerage Maintenance as we did for the 2014-based IPPS market basket, due to the small size of this estimated cost weight (approximately 0.1 percent).

(5) Professional Liability Insurance

We are proposing to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance medical liability premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the 2014-based IPPS market basket.

(6) Pharmaceuticals

We are proposing to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(7) Food: Direct Purchases

We are proposing to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(8) Food: Contract Services

We are proposing to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(9) Chemicals

Similar to the 2014-based IPPS market basket, we are proposing to use a four-part blended PPI as the proxy for the chemicals cost category in the proposed 2018-based IPPS market basket. The proposed blend is composed of the PPI Industry for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519-), and the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). We note that the four part blended PPI used in the 2014-based IPPS market basket is composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the

PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561–). For the 2018-based IPPS market basket, we are proposing to derive the weights for the PPIs using the 2012 Benchmark I–O data. The 2014-based IPPS market basket used the 2007 Benchmark I–O data to derive the weights for the four PPIs (82 FR 38164). We note that in the 2012 I–O data, the share of total chemicals expenses that the Soap and Cleaning Compound Manufacturing (NAICS 325610) represents decreased relative to the 2007 I–O data (from 5 percent to 2 percent), while the share of the total chemicals expenses that the All Other Chemical Product and Preparation manufacturing (NAICS 3259A0) categories represents increased (from 5 percent to 7 percent). As a result, we are proposing to remove the PPI Industry for Soap and Cleaning Compound Manufacturing from the proposed blend for the proposed 2018-based IPPS market basket and replace it with the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998).

Table IV–03 shows the proposed weights for each of the four PPIs used to create the blended index compared to those used for the 2014-based IPPS market basket.

TABLE IV-03.—BLENDED CHEMICAL PPI WEIGHTS

NAICS	Name	2014-Based IPPS Weights	Proposed 2018-Based IPPS Weights
325120	PPI Industry for Industrial Gas Manufacturing	32%	19%
325180	PPI Industry for Other Basic Inorganic Chemical Manufacturing	17%	13%
325190	PPI Industry for Other Basic Organic Chemical Manufacturing	45%	60%
325610	PPI Industry for Soap and Cleaning Compound Manufacturing	6%	n/a
325998	PPI Industry for Other Miscellaneous Chemical Product Manufacturing	n/a	8%

(10) Blood and Blood Products

We are proposing to use the PPI Industry for Blood and Organ Banks (BLS series code PCU621991621991) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(11) Medical Instruments

We are proposing to use a blended price proxy for the Medical Instruments category, as shown in Table IV–04. The 2012 Benchmark I–O data shows the majority of medical instruments and supply costs are for NAICS 339112—Surgical and medical instrument manufacturing costs (approximately 56 percent) and NAICS 339113—Surgical appliance and supplies manufacturing costs (approximately 43 percent). Therefore, we are proposing to use a blend of these two price proxies. To proxy the price changes associated with NAICS 339112, we propose using the PPI—Commodity—Surgical and medical instruments (BLS series code WPU1562). This is the same price proxy we used in the 2014-based IPPS market basket. To proxy the price changes associated with NAICS 339113, we are proposing to use a 50/50 blend of the PPI—Commodity—Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI—Commodity—Miscellaneous products—Personal safety equipment and clothing (BLS series code WPU1571). We are proposing to include the latter price proxy as it would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific expenses for these products; however, we recognize that this category reflects costs faced by IPPS hospitals.

TABLE IV-04.—BLENDED MEDICAL INSTRUMENTS PPI WEIGHTS

NAICS	Name	2014-Based IPPS Weights	Proposed 2018-Based IPPS Weights
339112	PPI - Commodity - Surgical and medical instruments	50%	56%
339113	PPI - Commodity - Medical and surgical appliances and supplies	50%	22%
	PPI - Commodity - Miscellaneous products-Personal safety equipment and clothing	n/a	22%

(12) Rubber and Plastics

We are proposing to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(13) Paper and Printing Products

We are proposing to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(14) Miscellaneous Products

We are proposing to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(15) Professional Fees: Labor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the 2014-based IPPS market basket.

(16) Administrative and Facilities Support Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same price proxy used in the 2014-based IPPS market basket.

(17) Installation, Maintenance, and Repair Services

We are proposing to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2014-based IPPS market basket.

(18) All Other: Labor-Related Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(19) Professional Fees: Nonlabor-Related

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same price proxy that we are proposing to use for the Professional Fees: Labor-Related cost category and the same price proxy used in the 2014-based IPPS market basket.

(20) Financial Services

We are proposing to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(21) Telephone Services

We are proposing to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same price proxy used in the 2014-based IPPS market basket.

(22) All Other: Nonlabor-Related Services

We are proposing to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the 2014-based IPPS market basket.

Table IV–05 sets forth the proposed 2018-based IPPS market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding 2014-based IPPS market basket cost weights also are listed.

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TABLE IV-05.—PROPOSED 2018-BASED IPPS MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO 2014-BASED IPPS MARKET BASKET COST WEIGHTS

Cost Categories	2014-Based IPPS Market Basket Cost Weights	Proposed 2018-Based IPPS Market Basket Cost Weights	Proposed 2018-Based IPPS Market Basket Price Proxies
1. Compensation	55.8	53.0	--
A. Wages and Salaries[1]	43.4	41.2	ECI for Wages and Salaries for All Civilian Workers in Hospitals
B. Employee Benefits[1]	12.4	11.7	ECI for Total Benefits for All Civilian Workers in Hospitals
2. Utilities	2.5	2.3	--
A. Electricity and Other Non-Fuel Utilities[2]	1.1	1.5	PPI Commodity for Commercial Electric Power
B. Fuel: Oil and Gas	1.3	0.8	Blend of PPIs for Petroleum Refineries and Natural Gas
3. Professional Liability Insurance	1.2	1.0	CMS Hospital Professional Liability Insurance Premium Index
4. All Other	40.5	43.8	--
A. All Other Products	17.4	18.4	--
(1.) Pharmaceuticals	5.9	7.1	PPI Commodity for Pharmaceuticals for Human Use, Prescription
(2.) Food: Direct Purchases	2.3	1.6	PPI Commodity for Processed Foods and Feeds
(3.) Food: Contract Services	1.3	1.8	CPI for Food Away From Home (All Urban Consumers)
(4.) Chemicals	0.9	0.6	Blend of Chemical PPIs
(5.) Blood and Blood Products	0.8	0.6	PPI Industry for Blood and Organ Banks
(6.) Medical Instruments	2.9	4.1	Blend of PPIs

Cost Categories	2014-Based IPPS Market Basket Cost Weights	Proposed 2018-Based IPPS Market Basket Cost Weights	Proposed 2018-Based IPPS Market Basket Price Proxies
(7.) Rubber and Plastics	0.8	0.6	PPI Commodity for Rubber and Plastic Products
(8.) Paper and Printing Products	1.5	0.9	PPI Commodity for Converted Paper and Paperboard Products
(9.) Miscellaneous Products	1.1	1.2	PPI Commodity for Finished Goods less Food and Energy
B. Labor-Related Services	12.5	14.7	--
(1.) Professional Fees: Labor-Related	6.8	8.6	ECI for Total Compensation for Private Industry Workers in Professional and Related
(2.) Administrative and Facilities Support Services	1.0	1.1	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
(3.) Installation, Maintenance and Repair Services	2.4	2.4	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair
(4.) All Other: Labor-Related Services	2.3	2.6	ECI for Total Compensation for Private Industry Workers in Service Occupations
C. Nonlabor-Related Services	10.7	10.7	--
(1.) Professional Fees: Nonlabor-Related	5.1	7.0	ECI for Total Compensation for Private Industry Workers in Professional and Related
(2.) Financial Services	3.0	1.4	ECI for Total Compensation for Private Industry Workers in Financial Activities
(3.) Telephone Services	0.8	0.4	CPI for Telephone Services
(4.) All Other: Nonlabor-Related Services	1.7	1.8	CPI for All Items less Food and Energy
Total	100.0	100.0	--

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

[2] We are proposing to include Water and Sewerage costs in the Electricity and Non-Fuel Utilities cost category in the proposed 2018-based IPPS market basket. These costs were broken out separately in the 2014-based IPPS market basket.

Table IV–06 compares both the historical and forecasted percent changes in the 2014-based IPPS market basket and the proposed 2018-based IPPS market basket. The forecasted growth rates in Table IV–06 are based on IHS Global Inc.'s (IGI's) fourth quarter 2020 forecast with historical data through third quarter 2020.

TABLE IV-06.--2014-BASED AND PROPOSED 2018-BASED IPPS HOSPITAL OPERATING INDEX PERCENT CHANGE, FY 2017 THROUGH FY 2024

Fiscal Year (FY)	2014-Based IPPS Market Basket Percent Change	Proposed 2018-Based IPPS Market Basket Percent Change
Historical data:		
FY 2017	2.6	2.5
FY 2018	2.5	2.5
FY 2019	2.4	2.4
FY 2020	2.0	2.0
Average FYs 2017-2020	**2.4**	**2.4**
Forecast:		
FY 2021	2.4	2.4
FY 2022	2.5	2.5
FY 2023	2.8	2.7
FY 2024	3.0	3.0
Average FYs 2021-2024	**2.7**	**2.7**

Source: IHS Global, Inc., 4th Quarter 2020 forecast.

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There is no difference between the average percent change in the 2014-based and the proposed 2018-based IPPS market basket over the FY 2017 through FY 2020 time period. For FY 2022, the increase is projected to be 2.5 percent for both the 2014-based and proposed 2018-based IPPS market baskets.

3. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments that are labor-related. Section 1886(d)(3)(E) of the Act states that the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.''

The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market.* For this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the proposed 2018-based IPPS market basket: Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, and All Other: Labor-Related Services, as we did in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38167).

Similar to the 2014-based IPPS market basket, we are proposing that the Professional Fees: Labor-Related cost category includes expenses associated with advertising and a proportion of legal services, accounting and auditing, engineering, and management consulting. As was done in the 2014-based IPPS market basket rebasing, we are proposing to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and received no comments (71 FR 8588).

A discussion of the composition of the survey and poststratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We are proposing to apply each of these percentages to its respective Benchmark I–O cost category underlying the professional fees cost category. This is the methodology that we used to separate the 2014-based IPPS market basket professional fees cost category into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We are proposing to use the same methodology and survey results to separate the professional fees costs for the proposed 2018-based IPPS market basket into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We believe these survey results are appropriate to use for the proposed 2018-based IPPS market basket as they empirically determine the proportion of contracted professional services purchased by the industry that is attributable to local firms and the proportion that is purchased from national firms.

In the proposed 2018-based IPPS market basket, nonmedical professional fees that were subject to allocation based on these survey results represent approximately 6.4 percent of total operating costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we are proposing to apportion 4.1 percentage points of the 6.4 percentage point figure into the

Professional Fees: Labor-Related share cost category and designate the remaining approximately 2.3 percentage points into the Professional Fees: Nonlabor-Related cost category.

In addition to the professional services listed earlier, we also classify a proportion of the Home Office/Related Organization cost weight into the Professional Fees: Labor-Related cost category as was done in the previous rebasing. We believe that many of these costs are labor-intensive and vary with the local labor market. However, data indicate that not all IPPS hospitals with home offices have home offices located in their local labor market. Therefore, we are proposing to include in the labor-related share only a proportion of the Home Office/Related Organization cost weight based on the methodology described in this rule.

For the proposed 2018-based IPPS market basket, based on Medicare cost report data, we found that approximately 65 percent of IPPS hospitals reported some type of home office information on their Medicare cost report for 2018 (for example, city, State, and zip code). Using the data reported on the Medicare cost report, we compared the location of the hospital with the location of the hospital's home office. We then determined the proportion of costs that should be allocated to the labor-related share based on the percent of total hospital home office/related organization contract labor costs for those hospitals that had home offices located in their respective local labor markets—defined as being in the same MSA. We determined a hospital's and home office's MSAs using their zip code information from the Medicare cost report.

Based on these data, we determined the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office/related organization contract labor costs (equal to the sum of Worksheet S–3, Part II, column 4, lines 14.01, 14.02, 25.50, and 25.51). Using this methodology, we determined that 60 percent of hospitals' home office compensation costs were for home offices located in their respective local labor markets. Therefore, we are proposing to allocate 60 percent of Home Office/Related Organization cost weight to the labor-related share. This is the same proportion we used for the 2014-based IPPS market basket, which was based on 2014 Medicare cost report data.

In the proposed 2018-based IPPS market basket, the Home Office/Related Organization cost weight that is subject to allocation based on the home office allocation methodology represent 5.9 percent of total operating costs. Based on the results of the home office analysis, as previously discussed, we are apportioning approximately 3.5 percentage points of the 5.9 percentage points figure into the Professional Fees: Labor-Related cost category and designating the remaining approximately 2.4 percentage points into the Professional Fees: Nonlabor-Related cost category. In summary, based on the two previously mentioned allocations, we apportioned 7.6 percentage points of the professional fees and home office cost weights into the Professional Fees: Labor-Related cost category. This amount is added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 1.0 percentage point of total operating costs) resulting in a Professional Fees: Labor-Related cost weight of 8.6 percent.

Table IV–07 presents a comparison of the proposed 2018-based labor-related share and the 2014-based labor-related share. As discussed in section IV.B.1.b. of the preamble of this proposed rule, the Wages and Salaries and Employee Benefits cost weights reflect contract labor costs.

TABLE IV-07.—COMPARISION OF THE 2014-BASED LABOR-RELATED SHARE AND THE PROPOSED 2018-BASED LABOR-RELATED SHARE

	2014-Based IPPS Market Basket Cost Weights	Proposed 2018-Based IPPS Market Basket Cost Weights
Wages and Salaries	43.4	41.2
Employee Benefits	12.4	11.7
Professional Fees: Labor-Related	6.8	8.6
Administrative and Facilities Support Services	1.0	1.1
Installation, Maintenance, and Repair Services	2.4	2.4
All Other: Labor-Related Services	2.3	2.6
Total Labor-Related Share	**68.3**	**67.6**

Note: Detail may not add to total due to rounding.

Using the cost category weights from the proposed 2018-based IPPS market basket, we calculated a labor-related share of 67.6 percent, approximately 0.7 percentage point lower than the current labor-related share of 68.3 percent. This downward revision to the labor-related share is the net effect of two impacts. First, we updated the base year cost weights from 2014 to 2018 (-1.8 percentage points), which reflects a -2.8 percentage point revision from the compensation cost weight and a +1.0 percentage point revision from the labor-related portion of Home Office/Related Organization Contract Labor cost weight (60 percent of total cost weight). Second, there is an upward revision of 1.1 percentage points from the impact of updating the detailed cost weights to reflect 2012 Input-Output data.

Therefore, we are proposing to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. We continue to believe, as we have stated in the past, that these operating cost categories are related to, influenced by, or vary with the local markets. Therefore, our definition of the

labor-related share continues to be consistent with section 1886(d)(3) of the Act. We note that section 403 of Pub. L. 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless 62 percent would result in lower payments to a hospital than would otherwise be made.

C. Market Basket for Certain Hospitals Presently Excluded From the IPPS

In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43857), we adopted the use of the FY 2006-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals and religious nonmedical health care institutions (RNHCIs). Children's hospitals and PPS-excluded cancer hospitals and RNHCIs are still reimbursed solely under the reasonable cost-based system, subject to the rate-of-increase limits. Under these limits, an annual target amount (expressed in terms of the inpatient operating cost per discharge) is set for each hospital based on the hospital's own historical cost experience trended forward by the applicable rate-of-increase percentages.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50603), under the broad authority in sections 1886(b)(3)(A) and (B), 1886(b)(3)(E), and 1871 of the Act and section 4454 of the BBA, consistent with our use of the IPPS operating market basket percentage increase to update target amounts, we adopted the use of the FY 2010-based IPPS operating market basket percentage increase to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, and RNHCIs that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40. In addition, as discussed in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50156 through 50157), consistent with §§ 412.23(g), 413.40(a)(2)(ii)(A), and 413.40(c)(3)(viii), we also used the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for short–term acute care hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). These hospitals also are paid on the basis of reasonable cost, subject to the rate-of-increase limits under § 413.40. In the FY 2018 IPPS/LTCH PPS final rule, we finalized the use of the 2014-based IPPS operating market basket for FY 2018 and subsequent fiscal years to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located outside the 50 states, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are paid on the basis of reasonable cost subject to the rate-of-increase limits under § 413.40. We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38170) for discussion of why we believe it is appropriate to use the percentage increase in the IPPS operating market basket to update the target amounts for these excluded facilities.

As discussed in this section IV. of the preamble of this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to rebase and revise the IPPS operating market basket to a 2018 base year. We continue to believe that it is appropriate to use the increase in the IPPS operating market basket to update the target amounts for these excluded facilities, as discussed in prior rulemaking. Therefore, we are proposing to use the percentage increase in the proposed 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located outside the 50 states, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of increase percentage to be applied to the target amount for these hospitals would be the FY 2022 percentage increase in the 2018-based IPPS operating market basket.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule (57 FR 40016). There have been subsequent discussions of the CIPI presented in the IPPS proposed and final rules. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38170 through 38175) described the most recent rebasing and revising of the CIPI to a 2014 base year, which reflected the capital cost structure of IPPS hospitals available at that time.

For the FY 2022 IPPS update, we are proposing to rebase and revise the CIPI to a 2018 base year to reflect a more current structure of capital costs for IPPS hospitals. This proposed 2018-based CIPI was derived using 2018 cost reports for IPPS hospitals, which includes providers whose cost reporting period began on or after October 1, 2017, and prior to September 30, 2018. We are also proposing to start with the same subset of Medicare cost reports from IPPS hospitals as previously described in section IV.B.1.a. of the preamble of this proposed rule. As with the 2014-based index, we are proposing to develop two sets of weights to derive the proposed 2018-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each expenditure category, while the second set of weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of the capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Using 2018 Medicare cost reports, we are able to obtain capital costs for the following categories: Depreciation, Interest, Lease, and Other. Specifically, we are proposing to determine what proportion of total capital costs that each category represents using the data reported by IPPS hospitals on Worksheet A–7, Part III. As shown in the left column of Table IV–08, in 2018 depreciation expenses accounted for 67.5 percent of total capital costs, interest expenses accounted for 14.6 percent, leasing expenses accounted for 13.3 percent, and other capital expenses accounted for 4.7 percent.

We also are proposing to allocate lease costs across each of the remaining capital cost categories as was done in the 2014-based CIPI. We are proposing to proportionally distribute leasing costs among the cost categories of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done for the 2014-based CIPI, we are proposing to assume that 10 percent of the lease costs as a proportion of total capital costs represents overhead and to assign those costs to the Other capital cost category accordingly. Therefore, we are assuming that approximately 1.3 percent (13.3 percent x 0.1) of total capital costs represent lease costs attributable to overhead, and we are proposing to add this 1.3 percent to the 4.7 percent Other cost category weight. We are then proposing to distribute the remaining lease costs (12.0 percent, or 13.3 percent—1.3 percent) proportionally across the three cost categories (Depreciation, Interest, and Other) based on the proportion that these categories comprise of the sum of

the Depreciation, Interest, and Other cost categories (excluding lease expenses). For example, the Other cost category represented 5.4 percent of all three cost categories (Depreciation, Interest, and Other) prior to any lease expenses being allocated. This 5.4 percent is applied to the 12.0 percent of remaining lease expenses so that another 0.6 percent of lease expenses as a percent of total capital costs is allocated to the Other cost category. Therefore, the resulting proposed Other cost weight is 6.6 percent (4.7 percent + 1.3 percent + 0.6 percent). This is the same methodology used for the 2014-based CIPI. The resulting cost weights of the proposed allocation of lease expenses are shown in the right column of Table IV–08.

TABLE IV-08.—PROPOSED ALLOCATION OF LEASE EXPENSES FOR THE PROPOSED 2018-BASED CIPI

Cost Categories	Proposed Cost Shares Obtained from Medicare Cost Reports (Percent of Total Capital Costs)	Proposed Cost Shares After Allocation of Lease Expenses (Percent of Total Capital Costs)
Depreciation	67.5	76.8
Interest	14.6	16.6
Lease	13.3	-
Other	4.7	6.6

Note: Detail may not add to 100 percent due to rounding

Finally, we are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also are proposing to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for IPPS hospitals (after the allocation of lease costs) that are attributable to building and fixed equipment, which we hereafter refer to as the ''fixed percentage.'' Based on Worksheet A–7, Part III data from the 2018 IPPS Medicare cost reports, we have determined that depreciation costs for building and fixed equipment account for approximately 51 percent of total depreciation costs, while depreciation costs for movable equipment account for approximately 49 percent of total depreciation costs. As was done for the 2014-based CIPI, we are proposing to apply this fixed percentage to the depreciation cost weight (after leasing costs are included) to derive a Depreciation cost weight attributable to Building and Fixed Equipment and a Depreciation cost weight attributable to Movable Equipment.

To disaggregate the interest cost weight, we needed to determine the percent of total interest costs for IPPS hospitals that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because interest price pressures tend to differ between nonprofit and for-profit facilities. We are proposing to use interest costs data from Worksheet A–7, Part III of the 2018 Medicare cost reports for IPPS hospitals, which is the same methodology used for the 2014-based CIPI. The nonprofit percentage determined using this method is 90 percent. Table IV–09 provides a comparison of the 2014-based CIPI cost weights and the proposed 2018-based CIPI cost weights.

After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. With the exception of the For-profit interest cost category, we are proposing to apply the same price proxies as were used in the 2014-based CIPI, which are listed in Table IV–09. We also are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2014-based CIPI and is described later in this section of this rule.

We are proposing to continue to proxy the Depreciation—Building and Fixed Equipment cost category by the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). As stated in the FY 2010 IPPS/LTCH final rule (74 FR 43860), for the FY 2006-based CIPI we finalized the use of this index to measure the price growth of this cost category. This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. For the Depreciation—Movable Equipment cost category, we are proposing to continue to measure the price growth using the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by hospitals including but not limited to communication equipment, computers, and medical equipment. For the Nonprofit Interest cost category, we are proposing to continue to measure the price growth using the average yield on domestic municipal bonds (Bond Buyer 20-bond index).

For the For-profit Interest cost category, we are proposing to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index that was used for the 2014-based IPPS market basket. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IGI, the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and MFP. Therefore, we are proposing to replace the price proxy for the For-profit Interest cost category. We compared the iBoxx AAA Corporate Bond Yield index with the Moody's AAA Corporate Bond Yield index and found that the average growth rates in the two series were similar. Over the historical time period of FY 2000 to FY 2020, the 4-quarter percent change moving average growth

in the iBoxx series was approximately 0.1 percentage point higher, on average, than the Moody's AAA corporate Bond Yield index.

For the Other capital cost category (including insurances, taxes, and other capital-related costs), we are proposing to continue to measure the price growth using the CPI for Rent of Primary Residence (All Urban Consumers) (BLS series code CUUS0000SEHA), which would reflect the price growth of these costs. We believe that these price proxies continue to be the most appropriate proxies for IPPS capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

TABLE IV-09.—PROPOSED 2018-BASED CIPI COST WEIGHTS AND PRICE PROXIES COMPARED TO 2014-BASED CIPI COST WEIGHTS

Cost Categories	2014 Cost Weights	Proposed 2018 Cost Weights	Proposed Price Proxy
Total	100.0	100.0	
Depreciation	74.4	76.8	
Building and Fixed Equipment	36.7	39.3	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care
Movable Equipment	37.7	37.5	PPI Commodity for Machinery and Equipment
Interest	18.2	16.6	
Government/Nonprofit	15.7	14.9	Average Yield on Domestic Municipal Bonds (Bond Buyer 20-Bond Index)
For-Profit	2.5	1.7	Average Yield on iBoxx AAA Corporate Bonds
Other	7.4	6.6	CPI for Rent of Primary Residence

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The proposed vintage-weighted 2018-based CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for IPPS capital costs. The CIPI reflects the underlying stability of the capital acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the previously noted components of capital purchases. The early Medicare cost reports did not have sufficient capital data to meet this need. Data we obtained from the American Hospital Association (AHA) did not include annual capital purchases. However, we were able to obtain data on total expenses back to 1963 from the AHA. Consequently, we are proposing to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We then are proposing to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2018. We are proposing to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derived annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. We used the AHA data and similar methodology to derive the 2014-based IPPS capital market basket.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2018-based CIPI. We are proposing to calculate the expected lives using Medicare cost report data. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 27 years, and the average expected life of movable equipment to be equal to 12 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that the 2014-based CIPI was also based on an expected average life of building and fixed

equipment of 27 years and an expected average life of movable equipment of 12 years.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we are proposing to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in this proposed rule. For the interest vintage weights, we are proposing to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital purchases time series specific to each asset type, we are proposing to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 27 years, and in the case of movable equipment, 12 years). For each asset type, we are proposing to use the time series of annual capital purchases amounts available from 2018 back to 1964. These data allow us to derive twenty-nine 27-year periods of capital purchases for building and fixed equipment and interest, and forty-four 12-year periods of capital purchases for movable equipment. For each 27-year period for building and fixed equipment and interest, or 12-year period for movable equipment, we are proposing to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 27-year or 12-year period. This calculation was done for each year in the 27-year or 12-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

The vintage weights for the proposed 2018-based CIPI and the 2014-based CIPI are presented in Table IV–10.

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TABLE IV-10.--PROPOSED 2018-BASED CIPI AND 2014-BASED CIPI VINTAGE WEIGHTS

Year[1]	Building and Fixed Equipment		Movable Equipment		Interest	
	Proposed 2018-Based 27 years	2014-Based 27 years	Proposed 2018-Based 12 years	2014-Based 12 years	Proposed 2018-Based 27 years	2014-Based 27 years
1	0.026	0.024	0.064	0.062	0.015	0.012
2	0.028	0.025	0.069	0.064	0.016	0.014
3	0.029	0.027	0.072	0.070	0.018	0.015
4	0.031	0.028	0.075	0.074	0.019	0.017
5	0.032	0.030	0.078	0.078	0.021	0.019
6	0.032	0.031	0.082	0.082	0.022	0.021
7	0.033	0.033	0.086	0.086	0.023	0.023
8	0.034	0.034	0.088	0.088	0.026	0.025
9	0.036	0.035	0.091	0.092	0.028	0.027
10	0.036	0.036	0.095	0.097	0.029	0.029
11	0.036	0.037	0.099	0.102	0.029	0.030
12	0.036	0.039	0.101	0.105	0.031	0.033
13	0.037	0.040	-	-	0.033	0.035
14	0.038	0.040	-	-	0.036	0.037
15	0.039	0.039	-	-	0.039	0.037
16	0.040	0.039	-	-	0.041	0.040
17	0.041	0.040	-	-	0.044	0.041
18	0.042	0.042	-	-	0.046	0.045
19	0.041	0.042	-	-	0.047	0.048
20	0.041	0.042	-	-	0.049	0.050
21	0.042	0.043	-	-	0.052	0.052
22	0.042	0.043	-	-	0.053	0.054
23	0.042	0.042	-	-	0.055	0.055
24	0.042	0.042	-	-	0.055	0.057
25	0.041	0.043	-	-	0.057	0.059
26	0.041	0.043	-	-	0.058	0.061
27	0.041	0.043	-	-	0.059	0.062
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

[1] Vintage weight in the last year (for example, year 27 for the proposed 2018-based CIPI) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 27 vintage weight would be applied to the 2022q3 fixed price proxy level, year 26 vintage weight would be applied to the 2021q3 fixed price proxy level, etc.

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The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table IV–10 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found under the following CMS website link: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

Table IV–11 in this section of this rule compares both the historical and forecasted percent changes in the 2014-based CIPI and the proposed 2018-based CIPI.

TABLE IV-11.—COMPARISON OF 2014-BASED AND PROPOSED 2018-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2017 THROUGH FY 2024

Fiscal Year	CIPI, 2014-Based	Proposed CIPI, 2018-Based
Historical Data:		
FY 2017	1.1	1.0
FY 2018	1.2	1.1
FY 2019	1.4	1.3
FY 2020	1.2	1.2
Average FYs 2017-2020	1.2	1.2
Forecast:		
FY 2021	1.0	0.9
FY 2022	1.0	1.0
FY 2023	1.2	1.1
FY 2024	1.3	1.2
Average FYs 2021-2024	1.1	1.1

Source: IHS Global, Inc., 4th quarter 2020 forecast.

IHS Global, Inc. forecasts a 1.0 percent increase in the proposed 2018-based CIPI for FY 2022, as shown in Table IV–11. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) based on the proposed 2018-based CIPI are included in Table IV–12.

TABLE IV-12.—PROPOSED 2018-BASED CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS-- FYs 2017 THROUGH 2024

Fiscal Year	Total	Depreciation	Interest
Historical Data:			
FY 2017	1.0	1.6	-2.4
FY 2018	1.1	1.6	-2.2
FY 2019	1.3	1.8	-1.9
FY 2020	1.2	1.8	-2.9
Forecast:			
FY 2021	0.9	1.7	-3.6
FY 2022	1.0	1.7	-3.7
FY 2023	1.1	1.7	-3.3
FY 2024	1.2	1.8	-3.1

Source: IHS Global, Inc., 4th quarter 2020 forecast.

Rebasing the CIPI from 2014 to 2018 did not have an impact on the percent change in the forecasted update for FY 2022 when rounded, as shown in Table IV–11.

V. Other Decisions and Changes to the IPPS for Operating Costs

A. Proposed Changes in the Inpatient Hospital Update for FY 2022 (§ 412.64(d))

1. Proposed FY 2022 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2022, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2021. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2022 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero.

We note, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets for FY 2022.

We are proposing to base the proposed FY 2022 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2020, which is estimated to be 2.5 percent. We also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2022 market basket update and the MFP adjustment in the final rule.

For FY 2022, we are proposing an MFP adjustment of 0.2 percentage point. Similar to the market basket update, for this proposed rule, we used IGI's fourth quarter 2020 forecast of MFP to compute the proposed FY 2022 MFP adjustment. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the MFP adjustment for the final rule.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the MFP adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

For FY 2022, we are proposing an MFP adjustment of 0.2 percentage point. Similar to the market basket update, for this proposed rule, we used IGI's fourth quarter 2020 forecast of the MFP adjustment to compute the proposed FY 2022 MFP adjustment. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the MFP for the final rule.

Based on these data, we have determined four proposed applicable percentage increases to the standardized amount for FY 2022, as specified in the following table:

PROPOSED FY 2022 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	2.5	2.5	2.5	2.5
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.625	-0.625
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.875	0	-1.875
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed **Applicable Percentage Increase Applied to Standardized Amount**	**2.3**	**0.425**	**1.675**	**-0.2**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. (Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).)

For FY 2022, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: a proposed update of 2.3 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.425 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.675 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.2 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As noted previously, for this proposed rule, we are using IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket update with historical data through third quarter 2020. Similarly, we used IGI's fourth quarter 2020 forecast of the MFP adjustment. We are proposing that if more recent data subsequently became available (for example, a more recent estimate of the market basket update and the MFP adjustment), we would use such data, if appropriate, to determine the update in the final rule.

2. Proposed FY 2022 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2022, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a 33⅓ percent reduction to three-fourths of the

applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the MFP adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the MFP adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2020 forecast of the proposed 2018 based IPPS market basket update with historical data through third quarter 2020, for this FY 2022 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we are proposing a market basket update of 2.5 percent and an MFP adjustment of 0.2 percent. Therefore, for FY 2022, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we have determined the following proposed applicable percentage increases to the standardized amount for FY 2022 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the FY 2022 operating standardized amount of 2.3 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent less an adjustment of 0.2 percentage point for the proposed MFP adjustment).

- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 1.675 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent, less an adjustment of 0.625 percentage point (the proposed market basket rate of-increase of 2.5 percent $\times$ 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.2 percentage point for the proposed MFP adjustment.

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the MFP adjustment for the FY 2022 IPPS/LTCH PPS final rule.

B. Rural Referral Centers (RRCs) Proposed Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and

- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Proposed Amendment to Timeframe Used for Case-Mix Index (CMI) Under § 412.96(c)(1) and § 412.96(h) and Discharges Under § 412.96(i) for RRC Classification

a. Case-Mix Index (CMI)

As previously noted, in addition to meeting other criteria, to qualify for initial RRC status for cost reporting periods beginning on or after October 1 of a given fiscal year, under § 412.96(c)(1), a hospital must meet the minimum case-mix index (CMI) value during the most recent Federal fiscal year that ended at least one year prior to the beginning of the cost reporting period for which the hospital is seeking RRC status. We typically use the data from the Federal fiscal year that is two years prior to the Federal fiscal year for which a hospital is seeking RRC status to compute the national and regional median CMI values, as these are generally the best available data at the time of the development of the proposed and final rules. For example, in the FY 2021 IPPS/LTCH PPS final rule, we calculated the national and regional median CMIs using discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019).

However, as discussed in section I.F. of this proposed rule, the best available data to use for certain purposes of this FY 2022 rulemaking may not be the FY 2020 data that we would ordinarily use, due to the impact of the COVID–19 PHE. We believe that the differences in utilization for certain types of services in FY 2020 as compared to what would have been expected in the absence of the PHE also affects the calculation of the CMI values used for purposes of determining RRC status. We note that the CMI values calculated using the FY

2020 data are significantly different from the CMI values calculated using the FY 2019 data. As such, while we would normally propose to use data from FY 2020 to calculate CMI values for this FY 2022 proposed rule, we are instead proposing to use values that are based on discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019), and include bills posted to CMS' records through March 2020. We are making available for public comment the CMI values calculated using the FY 2020 data that we would ordinarily propose to use. We refer readers to the ''Alternatives Considered'' discussion in section I.O. of Appendix A for where these and other supplemental files may be found.

Accordingly, we are proposing to amend § 412.96(c)(1) with regard to the data to be used in identifying the CMI value for an individual hospital that is used to determine whether the hospital meets the CMI criteria for purposes for RRC classification. Specifically, we are proposing to amend § 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We are also proposing to amend § 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria.

b. Discharges

As previously noted, in addition to meeting other criteria, to qualify for initial RRC status for cost reporting periods beginning on or after October 1 of a given fiscal year, under § 412.96(c)(2), a hospital must meet the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. We typically use the cost reporting periods that are 3 years prior to the fiscal year for which a hospital is seeking RRC status to compute the regional median discharges, as these are generally the latest cost report data available at the time of the development of the proposed and final rules. For example, in FY 2021 IPPS/LTCH PPS final rule, we calculated the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018.

However, as discussed in section I.F. of this proposed rule and as previously noted with respect to the CMI calculation, the best available data to use for certain purposes of this FY 2022 rulemaking may not be the FY 2019 cost report data that we would ordinarily use, due to the impact of the COVID–19 PHE. We believe that the differences in utilization for certain types of services in FY 2019 cost reporting periods that spanned the PHE as compared to what would have been expected in the absence of the PHE also affects the calculation of the regional median discharges used for purposes of determining RRC status. We note that the regional median discharges calculated using the FY 2019 cost report data are different from the regional median discharges values calculated using the FY 2018 data. As such, while we ordinarily would have proposed to calculate the regional median discharges based on cost reports with cost reporting periods beginning in FY 2019 (October 1, 2018 through September 30, 2019), we are instead proposing to calculate the regional median discharges based on cost reports with cost reporting periods beginning in FY 2018 (October 1, 2017 through September 30, 2018). We are making available for public comment the regional median discharges calculated using FY 2019 cost report data that we would ordinarily propose to use. We refer readers to the ''Alternatives Considered'' discussion in section I.O. of Appendix A for where these and other supplemental files may be found.

Accordingly, we are proposing to amend the regulations at § 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

2. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii), in conjunction with the proposed amendment to provide for the use of the best available data rather than the use of the latest available data. The proposed national median CMI value for FY 2022 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2022 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). For the reasons discussed previously, the proposed values are based on discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019), and include bills posted to CMS' records through March 2020.

In this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2021, they must have a CMI value for FY 2019 that is at least—

- 1.7049 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the table in this section of this rule. We may update the proposed CMI values in the FY 2022 final rule to reflect finalized policies for FY 2022, including the best available data.

Region	Proposed Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4447
2. Middle Atlantic (PA, NJ, NY)	1.5005
3. East North Central (IL, IN, MI, OH, WI)	1.60875
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.62455
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5777
6. East South Central (AL, KY, MS, TN)	1.54085
7. West South Central (AR, LA, OK, TX)	1.74375
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7833
9. Pacific (AK, CA, HI, OR, WA)	1.6913

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

3. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2022, consistent with our proposed amendments to § 412.96(i)(1) and (2) to provide for the use of the best available data rather than the latest available or most recent data, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018 (that is, October 1, 2017 through September 30, 2018). Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2021, must have, as the number of discharges for its cost reporting period that began during FY 2018, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. We refer readers to the proposed number of discharges in the table set forth in this section of the rule.

Region	Proposed Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,692
2. Middle Atlantic (PA, NJ, NY)	10,276
3. East North Central (IL, IN, MI, OH, WI)	8,787
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,647
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,616
6. East South Central (AL, KY, MS, TN)	9,134
7. West South Central (AR, LA, OK, TX)	6,288
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,774
9. Pacific (AK, CA, HI, OR, WA)	9,063

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

C. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate,

whichever results in a greater operating IPPS payment.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. (Section 50204 also extended prior changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals through FY 2018.) Currently, the low-volume hospital qualifying criteria provide that a hospital must have fewer 3,800 total discharges during the fiscal year, and the hospital must be located more than 15 road miles from the nearest ''subsection (d)'' hospital. These criteria will remain in effect through FY 2022. Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Therefore, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2022, it must have fewer than 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the **Federal Register** on April 26, 2018 (83 FR 18301 through 18308).)

2. Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2019 Through 2022

As discussed earlier, section 50204 of the Bipartisan Budget Act of 2018 further modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), to implement this requirement, we specified a continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment for FYs 2019 through 2022 is calculated using the following formula:

Low-Volume Hospital Payment Adjustment = $0.25 - [0.25/3300] \times$ (number of total discharges $- 500$) = $(95/330) -$ (number of total discharges/13,200).

For this purpose, we specified that the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment for FYs 2019 through 2022 is set forth in the regulations at 42 CFR 412.101(c)(3).

3. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking (for example, the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently

submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019 and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2022, as was the case for FYs 2019, 2020 and 2021, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year).[935] For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2022, we are proposing that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Consistent with historical practice, for FY 2022, we are proposing that a hospital's written request must be received by its MAC no later than September 1, 2021 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2021. If a hospital's written request for low-volume hospital status for FY 2022 is received after September 1, 2021, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2022 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination. We note that this proposal is generally consistent with the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2021 (85 FR 58802 through 58803).[936]

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2021 may continue to receive a low-volume hospital payment adjustment for FY 2022 without reapplying if it continues to meet the applicable mileage and discharge criteria (which, as discussed previously, are the same qualifying criteria that apply for FY 2021). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2022. (Determination of meeting the discharge criterion is discussed earlier in this section.) We note that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275). Consistent with historical policy, a hospital must submit its request, including this written verification, for each fiscal year for which it seeks to receive the low-volume hospital payment adjustment, and in accordance with the timeline described earlier.

D. Proposed Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2022, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2022 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

E. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2022 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment

[935] We note that for FY 2021, we established a deadline of September 15, 2020 for receipt of a hospital's written request by its MAC in order for the low-volume hospital payment adjustment to be applied to payments for a hospital's discharges beginning on or after October 1, 2020, as discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58803).

[936] As noted, CMS established a deadline of September 15, 2020 for receipt of the hospital's written request for FY 2021, as discussed in the FY 2021 IPPS/LTCH PPS final rule.

adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: The ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.'' In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus a statutory adjustment of 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining

those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. For this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to determine eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year using the best available data, consistent with our proposal discussed in section I.F of the preamble of this proposed rule. For a discussion of the inpatient Provider Specific File, we refer the reader to section II.A.4 of the Addendum of this proposed rule. In this FY 2022 IPPS/LTCH PPS proposed rule, we discuss our specific policies regarding eligibility to receive empirically justified Medicare DSH payments and uncompensated care payments for FY 2022 with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2022, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- *Sole community hospitals (SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we are proposing to continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the best available data). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a Factor 3 and an uncompensated care payment amount for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator of Factor 3 of the uncompensated care payment methodology will be based only on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.
- *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at:

https://innovation.cms.gov/initiatives/bpci-advanced/.

• *IPPS hospitals that participate in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. We refer the reader to the interim final rule with request for comments that appeared in the November 6, 2020 **Federal Register** for a discussion of the Model (85 FR 71167 through 71173). The Model's Performance Year 5 was extended to September 30, 2021.

• *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The Consolidated Appropriations Act of 2020 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the Rural Community Hospital Demonstration Program for an additional 5-year period. At the time of issuance of this proposed rule, we believe 27 hospitals may participate in the demonstration program at the start of FY 2022. Under the payment methodology that applies during the third 5-year extension period for the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments.

Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising the Medicare Administrative Contractors (MACs) to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this proposed rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2021, and our proposed policies for FY 2022.

a. Proposed Calculation of Factor 1 for FY 2022

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2021, in this FY 2022 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2022, we are proposing to

continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to the publication of our final projections in the FY 2022 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2022 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary (OACT) using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on OACT's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2019 through FY 2022 are discussed in the table titled ''Factors Applied for FY 2019 through FY 2022 to Estimate Medicare DSH Expenditures Using FY 2018 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of this FY 2022 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2021 Medicare DSH estimates, which were based on data from the September 2020 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2021 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2021 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the January 2021 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's January 2021 Medicare DSH estimates. The 27 hospitals that are anticipated to participate in the Rural Community Hospital Demonstration Program in FY 2022 were also excluded from these estimates, because under the payment methodology that applies during the third 5-year extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For this proposed rule, using the data sources as previously discussed, the Office of the Actuary's January 2021 estimate of Medicare DSH payments for FY 2022 without regard to the application of section 1886(r)(1) of the Act, is approximately $14.098 billion. Therefore, also based on the January 2021 estimate, the estimate of empirically justified Medicare DSH payments for FY 2022, with the application of section 1886(r)(1) of the Act, is approximately $3.524 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2022). Under § 412.l06(g)(1)(i) of the regulations, Factor 1 is the difference between these two OACT estimates . Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2022 would be $10,573,368,841.28, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2021 ($14,097,825,121.71 minus $3,524,456,280.43). We note that consistent with our approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2022 IPPS/LTCH PPS final rule.

The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget*. Consistent with historical practice, we expect that the Midsession Review will have updated economic assumptions and actuarial analysis, which would be used for the development of Factor 1 estimates in the final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections. (available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*).

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by the actuaries in determining OACT's estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to identify Medicare DSH payments, we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also includes a description of the ''Other'' and ''Discharges'' assumptions, and also provides additional information regarding how we address the Medicaid and CHIP expansion.

The Office of the Actuary's estimates for FY 2022 for this proposed rule began

with a baseline of $13.931 billion in Medicare DSH expenditures for FY 2018. The following table shows the factors applied to update this baseline through the current estimate for FY 2022:

Factors Applied for FY 2019 through FY 2022 to Estimate Medicare DSH Expenditures Using FY 2018 Baseline

FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2019	1.0185	0.97	1.009	1.0179	1.0147	14.136
2020	1.031	0.853	1.038	1.0023	0.9150	12.933
2021	1.029	0.968	0.998	0.9754	0.9696	12.541
2022	1.028	1.075	1.005	1.0122	1.1242	14.098

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2019 and FY 2020 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figure for FY 2021 is based on preliminary data. The discharge figure for FY 2022 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The discharge figures for FY 2020 to FY 2022 reflect the estimated impact of the COVID–19 pandemic. The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2019 and FY 2020 are based on actual data adjusted by a completion factor. The case-mix figure for FY 2021 is based on preliminary data. The case-mix factor figures for FY 2020 and FY 2021 have been adjusted for the estimated impact of the COVID–19 pandemic. The FY 2022 increase is an estimate based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on the information available at the time of development of this proposed rule, it is assumed that approximately 55 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2018, 2019, and 2020 resided in States that had elected to expand Medicaid eligibility, and approximately 60 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2021 and thereafter, resided in States that had elected to expand Medicaid eligibility. In the future, these assumptions may change based on actual participation by States. The ''Other'' column also includes the estimated impacts on Medicaid enrollment from the COVID–19 pandemic. We note that, based on the most recent available data, it is estimated that Medicaid enrollment increased by 2.9 percent in FY 2020 and will increase by an additional 1.2 percent in FY 2021.

For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on the most recent available data, OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 78 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. We note that this is an updated assumption based on more recent data compared to the data available at the time of the FY 2021 IPPS/LTCH PPS final rule. This same assumption was used for the new Medicaid beneficiaries who enrolled in 2020 and thereafter due to the COVID–19 pandemic. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2019	2.9	-0.75	-0.8	0.5	1.85
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0	0.5	2.9
2022	2.5		-0.2	0.5	2.8

Note: All numbers are from the inpatient hospital updates for the applicable year, except for the FY 2022 percentages, which are based on the most recent forecast. We refer readers to section V.A. of the preamble of this proposed rule for a complete discussion of the proposed changes in the inpatient hospital update for FY 2022.

b. Calculation of Proposed Factor 2 for FY 2022

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age.

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (1) The extent to which the source accounted for the full U.S. population; (2) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (3) the extent to which the source utilized data from the Census Bureau; (4) the timeliness of the estimates; (5) the continuity of the estimates over time; (6) the accuracy of the estimates; and (7) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We are proposing to use a methodology similar to the one that was used in FY 2018 through FY 2021 to determine Factor 2 for FY 2022.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the source that, on balance, best meets all of these considerations is the uninsured estimates produced by OACT as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the U.S., plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. For fiscal years 2014 through 2017, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the U.S. across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private

health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2019, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2019. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*. In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at: *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2019, OACT extrapolates from the 2009 CPS data through 2018 using data from the National Health Interview Survey (NHIS) and then, for 2019, OACT extrapolates using the American Community Survey (ACS). In deriving the number of uninsured for the most recent release of the national health expenditure accounts, there were two concerns related to the data sources typically used. The NHIS underwent a redesign in 2019 and cautioned its users against comparing the year-over-year trend from 2018–2019 as a result. Also, the Census Bureau indicated that it experienced data collection issues for the 2019 CPS, which may have been affected by the COVID–19 pandemic, and similarly cautioned its users to be aware of the potential impact on trend analysis between 2018 and 2019. Consequently, the ACS data were used for estimating 2019. The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). For both the NHIS and ACS, the U.S. Census Bureau is the data collection agent. The results from these data sources have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm.* For further information regarding the ACS, we refer readers to the Census Bureau's website at: *https://www.census.gov/programs-surveys/acs/*.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both CY 2021 and CY 2022. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections use the latest NHEA historical data, available at the time of their construction. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

The use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for this FY 2022 IPPS/LTCH proposed rule for further details on the methodology and assumptions that were used in the projection of the uninsurance rate.[937]

(2) Proposed Factor 2 for FY 2022

Using these data sources and the previously described methodologies, OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2021 and 2022 is 10.2 percent and 10.1 percent, respectively. The projected rates of uninsurance for CY 2021 and 2022 reflect the estimated impact of the COVID–19 pandemic. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates.

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we have used a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we are proposing to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2022.

[937] OACT Memorandum on Certification of Rates of Uninsured. March 12, 2021. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.*

OACT has certified the estimate of the rate of uninsurance for FY 2022 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. We may also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2022. We note that any potential impacts from the American Rescue Plan Act are not reflected in the following estimates, due to the timing for the development and publication of the FY 2022 IPPS/LTCH proposed rule.

The calculation of the proposed Factor 2 for FY 2022 is as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2021: 10.2 percent.

Percent of individuals without insurance for CY 2022: 10.1 percent.

Percent of individuals without insurance for FY 2022 (0.25 times 0.0102) + (0.75 times 0.0101): 10.1 percent.

1- |((0.101–0.14)/0.14)| = 1–0.2786 = 0.7214 (72.14 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation in order to determine Factor 2. Therefore, we are proposing that Factor 2 for FY 2022 would be 72.14 percent.

The proposed FY 2022 uncompensated care amount is $10,573,368,841.28* 0.7214 = $7,627,628,282.10.

Proposed FY 2022 Uncompensated Care Amount	$ 7,627,628,282.10

We are inviting public comments on the proposed Factor 2 for FY 2022.

c. Calculation of Proposed Factor 3 for FY 2022

(1) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year for which section 1886(r) of the Act was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report would potentially provide the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we used alternative data on the utilization of insured low-income patients, as measured by patient days, which we believed would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision to use proxy data was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011 and submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. However, we indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011

Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data reported on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. Our analyses on balance led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses. We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule.

We also recognized commenters' concerns that, in continuing to use Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care for FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. In the FY 2018 IPPS/LTCH PPS final rule, we finalized a methodology under which we calculated Factor 3 for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service (IHS) and Tribal hospitals, using Worksheet S–10 data from FY 2014 cost reports in conjunction with low-income insured days proxy data based on Medicaid days and SSI days. The time period for the Medicaid days data was FY 2012 and FY 2013 cost reports (82 FR 38208 through 38213).

As we stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41414), with the additional steps we had taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continued to believe that we could no longer conclude that alternative data to the Worksheet S–10 are currently available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Similarly, the actions that we have taken to improve the accuracy and consistency of the Worksheet S–10 data, including the opportunity for hospitals to resubmit Worksheet S–10 data for FY 2015, led us to conclude that there were no alternative data to the Worksheet S–10 data currently available for FY 2015 that would be a better proxy for the costs of subsection (d) hospitals for treating uninsured individuals. Accordingly, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41428), we advanced the time period of the data used in the calculation of Factor 3 forward by 1 year and used Worksheet S–10 data from FY 2014 and FY 2015 cost reports in combination with the low income insured days proxy for FY 2013 to determine Factor 3 for FY 2019. We note that, as discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42366), the use of three years of data to determine Factor 3 for FY 2018 and FY 2019 had the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), we received overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10. We began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule. The audits began with 1 year of data (that is, FY 2015 cost reports) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness. We chose to begin the audits with the FY 2015 cost reports primarily because this was the most recent year of data that we had broadly allowed to be resubmitted by hospitals, and many hospitals had already made considerable efforts to amend their FY 2015 reports in preparation for the FY 2019 rulemaking. We also considered that we had used the FY 2015 data as part of the calculation of the FY 2019 uncompensated care payments; therefore, the data had been subject to public comment and scrutiny.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use a single year of Worksheet S–10 cost report data from FY 2015 in the methodology for determining Factor 3 for FY 2020. Although some commenters expressed support for the alternative policy of using the FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules, emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. We also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58823 through 58825), we finalized our proposal to use the most recent available single year of audited Worksheet S–10 data to determine Factor 3 for FY 2021 and subsequent fiscal years. We explained our belief that using the most recent audited data available before the applicable Federal fiscal year, will more accurately reflect a hospital's uncompensated care costs, as opposed to averaging multiple years of data. We noted that if a hospital has relatively different data between cost report years, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3. Therefore, we also believed using a single year of audited cost report data is an appropriate methodology to determine Factor 3 for FY 2021 and subsequent years, except for IHS and Tribal hospitals and hospitals located in Puerto Rico. For IHS and Tribal hospitals and Puerto Rico hospitals, we finalized the use of a low-income insured days proxy to determine Factor 3 for FY 2021. We did not finalize a

methodology to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals for FY 2022 and subsequent years because we believed further consideration and review of these hospitals' Worksheet S–10 data was necessary (85 FR 58825).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized the definition ''uncompensated care'' for FY 2021 and subsequent fiscal years, for purposes of determining uncompensated care costs and calculating Factor 3 (85 FR 58825 through 58828). We are continuing to use the definition that we had initially adopted in the FY 2018 IPPS/LTCH PPS final rule. Specifically, ''uncompensated care'' is defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). We refer readers to the FY 2021 IPPS/LTCH PPS rule (85 FR 58825 through 58828) for a discussion of additional topics related to the definition of uncompensated care. We noted in the FY 2021 IPPS/LTCH PPS final rule that the Paper Reduction Act (PRA) package for Form CMS–2552–10 (OMB Control Number 0938–0050, expiration date March 31, 2022) would offer an additional opportunity to comment on the cost reporting instructions. A PRA package with comment period appeared in the November 10, 2020 **Federal Register** (85 FR 71653). We thank stakeholders for their comments on the PRA package and we will respond to those comments in a separate **Federal Register** document.

(2) Background on the Methodology Used to Calculate Factor 3 for FY 2021 and Subsequent Fiscal Years

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2021 IPPS/LTCH PPS final rule, we applied the following policies as part of the Factor 3 methodology: (1) The policy regarding newly merged hospitals that was initially adopted in the FY 2015 IPPS/LTCH PPS final rule; (2) the policies regarding annualization and long cost reports that were adopted in the FY 2018 and FY 2019 IPPS/LTCH PPS final rules, including a modified policy for the rare cases where a provider has no cost report for the fiscal year that is used in the Factor 3 methodology because the cost report for the previous fiscal year spans both years; (4) the modified new hospital policy that was finalized in the FY 2020 IPPS/LTCH PPS final rule; (5) the new merger policy adopted in the FY 2021 IPPS/LTCH PPS final rule that accounts for the merger effective date; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829), we continued to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year would be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with past policy, interim uncompensated care payments for newly merged hospitals are based only on the data for the surviving hospital's CCN available the time of the development of the final rule. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2021 cost report. That is, we will revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2021 cost report.

In FY 2021 IPPS/LTCH PPS final rule (85 FR 58829), we continued the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data, except in the case of mergers, which would be subject to the modified merger policy adopted for FY 2021. In addition, we continued the policies that were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415) regarding the use of the longest cost report available within the Federal fiscal year. However, we adopted a modified policy for those rare situations where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. Under this modified policy, we use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data from the latter fiscal year are used in the Factor 3 methodology.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58829 and 58830), we continued the modified new hospital policy for new hospitals that did not have data for the cost reporting period(s) used in the Factor 3 calculation for FY 2021. Under the modified policy originally adopted for FY 2020, new hospitals that have a preliminary projection of being eligible for Medicare DSH based on their most recent available disproportionate patient percentages may receive interim empirically justified DSH payments. However, because these hospitals did not have a FY 2017 cost report to use in the Factor 3 calculation and the projection of eligibility for DSH payments was still preliminary, the MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2021 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2021, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care

costs reported on Worksheet S–10 of the hospital's FY 2021 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2017 cost reports for all DSH-eligible hospitals.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a new merger policy that accounts for the merger effective date (85 FR 58828 through 58829). To more accurately estimate UCC for the hospitals involved in a merger when the merger effective date occurs partway through the surviving hospital's cost reporting period, we finalized a policy of not annualizing the acquired hospital's data. Under this policy, we use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. To do this, we calculate a multiplier to be applied to the acquired hospital's UCC. This multiplier represents the portion of the UCC data from the acquired hospital that should be incorporated with the surviving hospital's data to determine UCC for purposes of determining Factor 3 for the surviving hospital. This multiplier is obtained by calculating the number of days between the start of the applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. Applying this multiplier to the acquired hospital's unannualized UCC data will determine the final portion of the acquired hospital's UCC that should be added to that of the surviving hospital for purposes of determining Factor 3 for the merged hospital.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831 and 58832), we continued to apply a CCR trim methodology similar to the CCR trim methodology policy that has been used for purposes of determining uncompensated care payments since FY 2018. This CCR trim methodology is consistent with the approach used in the outlier payment methodology under § 412.84(h)(3)(ii), which states that the Medicare contractor may use a statewide average CCR for hospitals whose operating or capital CCR is in excess of 3 standard deviations above the corresponding national geometric mean. We refer readers to the discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831) for a detailed description of the steps used to determine the applicable CCR.

In addition, we continued the UCC data trim methodology for rare situations where a hospital has potentially aberrant data that are unrelated to its CCR (85 FR 58832). However, because we had audited the FY 2017 Worksheet S–10 data for a number of hospitals, we explained that we no longer believe it is necessary to apply the trim methodology for hospitals whose cost report has been audited. Accordingly, for FY 2021 we finalized a policy under which we exclude hospitals that were part of the audits from the trim methodology for potentially aberrant UCC. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831), we also modified the potentially aberrant UCC trim methodology when it is applied to all-inclusive rate providers (AIRPs). Under this modified trim methodology, when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its FY 2017 cost report, we will recalculate the AIRP's UCC using the CCR reported on Worksheet S–10, line 1 of the hospital's most recent available prior year cost report that does not result in UCC of over 50 percent of total operating costs.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58824 and 58825), we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3 for IHS and Tribal hospitals and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58817) for a discussion of the approach that we continued in FY 2021 to determine Factor 3 for new Puerto Rico hospitals. In brief, Puerto Rico hospitals that do not have a FY 2013 cost report are considered new hospitals and subject to the new hospital policy, as discussed previously. Specifically, the numerator of the Factor 3 calculation will be the uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the applicable fiscal year and the denominator is the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals.

Therefore, for FY 2021, we finalized the following methodology to compute Factor 3 for each hospital:

Step 1: Selecting the provider's longest cost report from its Federal fiscal year (FFY) 2017 cost reports. (Alternatively, in the rare case when the provider has no FFY 2017 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2017 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualizing the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combining adjusted and/or annualized uncompensated care costs for hospitals that merged.

Step 4: Calculating Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals that have a FY 2013 cost report using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). (Alternatively, in the rare case when a provider has no FFY applicable cost report because the cost report for the previous Federal fiscal year spanned the time period, the previous Federal fiscal year cost report would be used in this step.) The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals. Consistent with the policy adopted in the FY 2019 IPPS/LTCH PPS final rule, if a hospital did not have both Medicaid days for FY 2013 and SSI days for FY 2018 available for use in the calculation of Factor 3 in Step 4, we considered the hospital not to have data available for Step 4.

Step 5: Calculating Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2017 cost report data (from Step 1, 2, or 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We also stated that the methodology adopted in the FY 2021 IPPS/LTCH PPS final rule for purposes of determining Factor 3 for FY 2021 would apply for FY 2022 and subsequent years, using Worksheet S–10 data from the most recent cost reporting year for which audits have been conducted. However,

we did not finalize a methodology to determine Factor 3 for FY 2022 and subsequent years for IHS and Tribal hospitals and Puerto Rico hospitals that have a FY 2013 cost report because we believed further consideration and review of these hospitals' Worksheet S–10 data is necessary.

We amended the regulations at § 412.106(g)(1)(iii)(C) by adding a new paragraph (7) to reflect the methodology for computing Factor 3 for FY 2021. We also added a new paragraph (8) to reflect the policy adopted for all subsequent fiscal years of using the most recent available single year of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals, except IHS and Tribal hospitals and Puerto Rico Hospitals.

(3) Proposed Methodology for Calculating Factor 3 for FY 2022

(a) Use of Audited FY 2018 Data To Calculate Factor 3 for FY 2022

Audits of FY 2018 cost reports began in 2020 and those audited reports are now available, in time for the development of this proposed rule. Feedback from the audits of the FY 2015 and FY 2017 reports and lessons learned were incorporated into the audit process for the FY 2018 reports. We again chose to audit 1 year of data (that is, FY 2018) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness.

Given that the FY 2018 Worksheet S–10 data are the most recent available audited data, we believe, on balance, that the FY 2018 Worksheet S–10 data are the best available data to use for calculating Factor 3 for FY 2022. As discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules (84 FR 19419 and 84 FR 42364), we continue to believe that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. To the extent that the audited FY 2018 data for a hospital may be relatively different from its FY 2017 data (whether audited or unaudited), we potentially would be diluting the effect of the revisions to the cost reporting instructions and our considerable auditing efforts, while introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3 for FY 2022. We recognize that the FY 2017 reports include audited data for some hospitals. However, the FY 2018 cost reports are the most recent year of audited data and, and reflect the revisions to the Worksheet S–10 cost report instructions that were effective on October 1, 2017.

Accordingly, consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule and codified in the regulations at § 412.106(g)(8), we have used a single year of Worksheet S–10 data from FY 2018 cost reports to calculate Factor 3 for FY 2022 for all eligible hospitals with the exception of IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013. As discussed in a later section, we are proposing to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for one more year. We note that the proposed uncompensated care payments to hospitals whose FY 2018 Worksheet S–10 data have been audited represent approximately 99.6 percent of the proposed total uncompensated care payments for FY 2022. For purposes of this FY 2022 proposed rule, we have used a HCRIS extract updated through February 19, 2021. We note that we intend to use the March 2021 update of HCRIS for the FY 2022 final rule and the respective March updates for all future final rules. However, we may consider the use of more recent data that may become available after March 2021, but prior to the development of the final rule, if appropriate, for purposes of calculating the final Factor 3 for the FY 2022 IPPS/LTCH PPS final rule.

- IHS and Tribal Hospitals

For the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), we continue to recognize that the use of data from Worksheet S–10 to calculate the uncompensated care amount for IHS and Tribal hospitals may jeopardize these hospitals' payments due to their unique funding structure. Prior to the proposed rulemaking for FY 2022, CMS consulted with IHS and Tribal hospitals regarding uncompensated care reporting. We are considering the input received through this consultation with IHS and Tribal hospitals for future rulemaking.

Therefore, for IHS and Tribal hospitals, we propose to continue the policy first adopted in the FY 2018 rulemaking regarding the low-income patient proxy. Specifically, for FY 2022 we propose to determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent available year of data on SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. We continue to believe this approach is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. We also note that all IHS and Tribal hospitals have a FY 2013 cost report that can be used for purposes of determining Factor 3. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a HCRIS extract updated through February 19, 2021, and the FY 2018 SSI days.

- Puerto Rico Hospitals

In the FY 2021 IPPS/LTCH PPS proposed rule, we proposed to determine Factor 3 for Puerto Rico hospitals using Worksheet S–10 data starting in FY 2022. We did not finalize this proposal in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58825) because we believed further consideration was necessary. However, we noted that we continued to believe Worksheet S–10 data is the appropriate long term source for information on uncompensated care for hospitals located in Puerto Rico.

We are continuing to consider the reporting challenges in Puerto Rico that may negatively impact the ability of Puerto Rico hospitals to report uncompensated care. Accordingly, for FY 2022 we are proposing to determine Factor 3 for Puerto Rico hospitals that have a FY 2013 cost report based on the low-income patient proxy. We would determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent available year of data on SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a recent HCRIS extract and the most recent available data on SSI days, which was the FY 2018 SSI days. In addition, because we are proposing to continue to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we are proposing to continue to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days, as finalized in the FY

2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

(b) Methodology for Calculating Factor 3 for FY 2022

For purposes of determining Factor 3 for FY 2022, we will apply the methodology adopted in the FY 2021 IPPS/LTCH PPS final rule. Specifically, we are applying the following policies: (1) The merger policies that were initially adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), as modified in the FY 2021 IPPS/LTCH PPS final rule to incorporate the use of a multiplier to account for merger effective date; (2) the policy for providers with multiple cost reports, beginning in the same fiscal year, of using the longest cost report and annualizing Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy, as modified in the FY 2021 IPPS/LTCH PPS final rule, for the rare case where a hospital has a cost report that starts in one fiscal year and spans the entirety of the following fiscal year, such that the hospital has no cost report for that subsequent fiscal year, of using the cost report that spans both fiscal years for the latter fiscal year; (4) the new hospital policy, as modified in the FY 2020 IPPS/LTCH PPS final rule; (5) the newly merged hospital policy; and (6) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

• New Hospital for Purposes of Factor 3

We will continue to apply the new hospital policy that was initially adopted in the FY 2020 IPPS/LTCH PPS final rule to determine Factor 3 for new hospitals that do not have an FY 2018 cost report to use in the Factor 3 calculation (that is, hospitals with CCNs established on or after October 1, 2018). In the FY 2020 IPPS/LTCH PPS final rule, we modified the new hospital policy that was initially adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50643) and continued to apply through FY 2019 (83 FR 41417). Under this modified policy, if a new hospital has a preliminary projection of being eligible for DSH payments based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments during FY 2022 because we will have no FY 2018 uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2022 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2022, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2022 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2018 cost reports for all DSH-eligible hospitals. This denominator will be the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals, with the exception of Puerto Rico hospitals and IHS and Tribal hospitals.

• Newly Merged Hospitals

We are continuing to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals (79 FR 50021 and 50022). Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, we will continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation.

Consistent with past policy, interim uncompensated care payments for the newly merged hospital will be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule. In other words, for FY 2022, the eligibility of a newly merged hospital to receive interim uncompensated care payments and the amount of any interim uncompensated care payments, will be based only on the FY 2018 cost report available for the surviving CCN at the time the final rule is developed. However, at cost report settlement, we will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2022 cost report. That is, we will revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2022 cost report.

• CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). Consistent with the process for trimming CCRs used in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58831 and 58832), we will apply the following steps to determine the applicable CCR:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: For FY 2018 cost reports, calculate a CCR ''ceiling'' with the following data: For each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2018 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for FY 2018 greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For this proposed rule, the statewide average CCR was applied to 10 hospitals, of which 3 hospitals had FY 2018 Worksheet S–10 data.

Step 5: For providers that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR as determined in step 3.

After completing the previously described steps, we re-calculate the hospital's uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

• Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, we note that there are rare situations where a hospital has potentially aberrant data that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant UCC that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 final rule (85 FR 58832), if the hospital's uncompensated care costs for FY 2018 are an extremely high ratio (greater than 50 percent) of its total operating costs, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. Specifically, if the hospital's FY 2018 cost report is determined to include potentially aberrant data, data from the FY 2019 cost report will be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2018 will be trimmed by multiplying its FY 2018 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2019 cost report to calculate an estimate of the hospital's uncompensated care costs for FY 2018 for purposes of determining Factor 3 for FY 2022.

We note that we have audited the FY 2018 Worksheet S–10 data for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, consistent with the policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule, it is unnecessary to apply the trim methodology for these audited hospitals.

In addition to the existing UCC trim methodology, we are proposing to apply a new trim specific to certain hospitals that do not have audited FY 2018 Worksheet S–10 data. We note that in rare cases, hospitals that are not currently projected to be DSH eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). We are proposing to use a threshold of three standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold of $7 million, which is the median total uncompensated care cost reported on FY 2018 cost reports for hospitals that are projected to be DSH eligible, excluding IHS and Tribal hospitals and Puerto Rico hospitals. Therefore, for FY 2022, we are proposing that in the rare case that a hospital's insured patients' charity care costs are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent (rounded from 58 percent), we would exclude the hospital from the prospective Factor 3 calculation. This proposed trim would only impact hospitals that are not currently projected to be DSH eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for projected DSH eligible hospitals. If a hospital would be trimmed under both the existing UCC trim methodology and this proposed new trim, we are proposing to apply this new trim in place of the existing UCC trim methodology. We believe the proposed new trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the existing trim, because the existing trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

In addition, we also propose that, for the hospitals that would be subject to this proposed trim, if the hospital is ultimately determined to be DSH eligible at cost report settlement, then the MAC would calculate a Factor 3 after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2022 cost report. We believe if a hospital subject to this proposed trim is ultimately determined to be DSH eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2022 Worksheet S–10 has been reviewed. We note that this approach is comparable to the policy for new hospitals for which we cannot calculate a prospective Factor 3 because they do not have Worksheet S–10 data for the relevant fiscal year.

• Summary of Methodology

In summary, for FY 2022, we will compute Factor 3 for each hospital using the following steps:

Step 1: Select the provider's longest cost report from its Federal fiscal year (FFY) 2018 cost reports. (Alternatively, in the rare case when the provider has no FFY 2018 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2018 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013 using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculate Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2018 cost report data (from Step 1, 2 or 3). New hospitals and the hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We are proposing to amend the regulation at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*9*) to reflect the methodology for computing Factor 3 for FY 2022 for IHS and Tribal hospitals and for Puerto Rico hospitals that have a 2013 cost report. We also are proposing to make a conforming change to limit the reference to Puerto Rico hospitals in paragraph (g)(1)(iii)(C)(8) to those Puerto Rico hospitals that have a cost report for 2013.

(c) Proposal Related to the Per Discharge Amount of Interim Uncompensated Care Payments

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per discharge basis. We have used a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year, is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

We are proposing to modify this calculation for FY 2022 to be based on the average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that includes data from FY 2018, FY 2019, and FY 2020. We believe computing a 3-year average with the FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the pandemic. Under this proposal, the resulting 2-year average of discharges would be used to calculate the per discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH eligible hospital during FY 2022. The interim uncompensated care payments made to a hospital during the fiscal year are reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the Federal fiscal year.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), we finalized a voluntary process through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount is not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule, the hospital's MAC would evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the historical average number of discharges is lower than hospital's projected FY 2022 discharges. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the Federal fiscal year. We refer readers to the Addendum to this proposed rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

(d) Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this proposed rule, we will publish on the CMS website a table listing Factor 3 for all hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2022 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for the hospitals that would be subject to the proposed new trim, which is similar to the approach for new hospitals, which also do not have a Factor 3 published. At the time of development of this proposed rule, the FY 2019 SSI ratios were not available. Accordingly, we computed Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals using the most recent available data regarding SSI days from the FY 2018 SSI ratios. If more recent data become available, then we would use such data in the final rule.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the ten hospitals that would be subject to the proposed new trim, with a N/A in the Factor 3 column.

Hospitals have 60 days from the date of public display of the FY 2022 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of the Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling or most recent report differs from previously accepted amended report due to MAC mishandling). Comments raising issues that are specific to the information included in the table and supplemental data file can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. All other comments submitted in response to our proposed policies for determining uncompensated care payments for FY 2022 must be submitted in one of three ways found in the **ADDRESSES** section of this proposed rule before the close of the comment period in order to be assured consideration. In addition, this CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs. We will address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in

conjunction with the publication of the FY 2022 IPPS/LTCH PPS final rule.

For FY 2022, we are again proposing that hospitals will have 15 business days from the date of public display of the FY 2022 IPPS/LTCH PPS final rule in the **Federal Register** to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. Any changes to Factor 3 would be posted on the CMS website and would be effective beginning October 1, 2021. We continue to believe that hospitals have sufficient opportunity during the comment period for the proposed rule to provide information about recent and/or pending mergers and/or to report upload discrepancies. Hospitals do not enter into mergers without advanced planning. A hospital can inform CMS during the comment period for the proposed rule regarding any merger activity not reflected in supplemental file published in conjunction with the proposed rule. As discussed in an earlier section, we currently expect to use data from the March 2021 HCRIS extract for the FY 2022 final rule, which contributes to our increased confidence that hospitals would be able to comment on mergers and report any upload discrepancies during the comment period for this proposed rule. However, we also noted that we may consider using more recent data that may become available after March 2021, but before the final rule for the purpose of calculating the final Factor 3s for the FY 2022 IPPS/LTCH PPS final rule. In the event that there are any remaining merger updates and/or upload discrepancies after the final rule, the 15 business days from the date of public display of the FY 2022 IPPS/LTCH PPS final rule deadline should allow for the time necessary to prepare and make any corrections to Factor 3 calculations before the beginning of the Federal fiscal year.

We are inviting public comments on our proposed methodology for calculating Factor 3 for FY 2022, including, but not limited to, our proposed use of FY 2018 Worksheet S–10 data.

F. Counting Days Associated With Section 1115 Demonstration Projects in the Medicaid Fraction

Some States extend medical coverage benefits under a section 1115(a) demonstration project (also referred to as a section 1115 waiver) to populations that could not have been made eligible for medical assistance under the Medicaid State plan. These populations, commonly referred to as expansion populations or expansion waiver groups, are specific, finite populations defined in the waiver approval letters and special terms and conditions for each demonstration project.

On January 20, 2000, we issued an interim final rule with comment period (65 FR 3136) (hereinafter, January 2000 interim final rule), followed by a final rule issued on August 1, 2000 (65 FR 47086 through 47087), that changed the Secretary's policy on how to treat the patient days of all populations that receive medical coverage benefits under a section 1115 demonstration project in calculating the Medicare DSH adjustment. Previously, hospitals could include only the days for those populations receiving medical coverage benefits under a section 1115 demonstration project who were, or could have been made, eligible for Medicaid under the State plan. Patient days of those expansion waiver groups who were not and could not be made eligible for medical assistance under the State plan were not to be included for purposes of determining Medicaid patient days in calculating the Medicare DSH patient percentage.

Under the new policy adopted in the January 2000 interim final rule (65 FR 3137), hospitals could include in the numerator of the Medicaid fraction all patient days of populations eligible for Title XIX for which matching payment through a section 1115 expansion waiver demonstration project is made, whether or not those individuals were or could be made eligible for medical assistance under a State plan. This policy was effective for discharges occurring on or after January 20, 2000. In the January 2000 interim final rule (65 FR 3137), we explained that allowing hospitals to include patient days for section 1115 expansion populations in the Medicare DSH calculation is fully consistent with the Congressional goals of the Medicare DSH adjustment to recognize the higher costs to hospitals of treating low-income individuals covered under Medicaid.

In the FY 2004 IPPS final rule (68 FR 45420 and 45421), we further revised our regulations in order to limit the types of section 1115 waiver programs for which patient days could be counted in the numerator of the Medicaid fraction. We explained that in allowing hospitals to include patient days of section 1115 expansion waiver populations, our intention was to include patient days of those populations who, under a demonstration project, receive benefits, including inpatient hospital coverage benefits, that are similar to the benefits provided to traditional Medicaid beneficiaries. We had become aware, however, that certain section 1115 demonstration projects serve expansion populations with benefit packages so limited that the benefits are unlike the relatively expansive health care insurance coverage provided under a Medicaid State plan. We explained that these limited section 1115 demonstration projects extend coverage only for specific services and do not include insurance coverage for inpatient hospital care. We noted that due to the limited nature of the coverage provided under the section 1115 waiver, these expansion populations could have significantly higher incomes than traditional Medicaid beneficiaries. Because of the limited nature of the medical coverage benefits provided to expansion populations under these waivers, as compared to the benefits provided to the traditional Medicaid population under a State plan, and the possible difference in income levels between the expansion populations in limited benefit demonstrations and traditional Medicaid beneficiaries, we determined it was appropriate to exclude patient days of patients provided limited benefits under a section 1115 waiver from the determination of Medicaid days for purposes of the DSH calculation. Specifically, we revised the language of § 412.106(b)(4)(i) to provide that for purposes of determining the Medicaid fraction, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a section 1115 waiver. Thus, under our current regulations, hospitals are allowed to count patient days in the numerator of the Medicaid fraction only if they are days of patients eligible for inpatient hospital services under either a State Medicaid plan or section 1115 expansion waiver, who are not also entitled to benefits under Medicare Part A.

In the FY 2004 IPPS final rule, we specifically discussed family planning benefits offered under a section 1115 waiver as an example of the kind of waiver program that should not be counted in the Medicaid fraction because the benefits granted to the expansion population are too limited and, therefore, might be offered to populations with significantly higher incomes. Our intention was to provide a concrete example of how the changes being made in the FY 2004 IPPS final rule would refine the Secretary's policy to allow only the days of those expansion waiver populations who are provided medical coverage benefits, and

specifically coverage of inpatient hospital care, like the health care coverage that traditional Medicaid beneficiaries receive under a State plan, to be included in the numerator of the Medicaid fraction of the Medicare DSH calculation. While we specifically discussed section 1115 waiver family planning benefits, it was our intention that they would serve as an illustrative example of the kind of benefits offered through a section 1115 waiver program that are so limited that the patients receiving them should not be considered eligible for Medicaid for purposes of the DSH calculation.

In 2005, the Ninth Circuit held that expansion populations receive care ''under the State plan'' and that, accordingly, our pre-2000 practice of excluding them from the numerator of the Medicaid fraction was contrary to the plain language of the Act.[938] Subsequently, the District Court for the District of Columbia reached the same conclusion, reasoning that if our policy of counting the days of expansion populations after 2000 was correct, then patients in expansion populations were necessarily ''eligible for medical assistance under a State plan'' (that is Medicaid) and the Act had always required their inclusion.[939]

Shortly thereafter, in early 2006, Congress enacted the Deficit Reduction Act of 2005 (''the DRA''). Section 5002 of the DRA amended section 1886(d)(5)(F)(vi) of the Act to clarify our authority to include or exclude expansion populations from the DSH calculation, effectively overruling the earlier court decisions. Section 5002(a) of the DRA clarified that expansion populations receiving Medicaid benefits were *not* ''eligible for medical assistance under a State plan'' by referring to them as ''not so eligible.'' The statute made explicit that the Secretary nevertheless has the discretion to ''regard'' certain expansion populations as being ''eligible for medical assistance under a State plan'' for the purpose of the DSH calculation, and to include them in the numerator of the Medicaid fraction ''to the extent and for the period the Secretary determines appropriate.'' Section 5002(b) of the DRA expressly ratified our pre-2000 policy of not including expansion populations unless they could have been made eligible for Medicaid. As discussed, at the time the DRA was enacted, CMS ''regarded'' only a small subset of expansion populations as being eligible for Medicaid: Those who were eligible to receive inpatient hospital insurance benefits under the terms of the expansion waiver. In light of that history, we have not understood the DRA to grant CMS the authority to include in the DSH calculation any patient who in any way benefits from a section 1115 demonstration project. Rather, our authority under section 1886(d)(5)(F)(vi) of the Act remains limited to including expansion populations—that is, patients who can be ''regarded'' as ''eligible for medical assistance under a State plan approved under title XIX'' (that is, Medicaid) because they receive benefits through a section 1115 demonstration project that are comparable to traditional Medicaid benefits.

More recently, section 1115 demonstration projects have been used to authorize the funding of uncompensated care pools that help to offset the burden that treating the uninsured places on hospitals. These pools do not extend Medicaid benefits to uninsured individuals. Unlike demonstration projects that expand the population of people who are entitled to Medicaid benefits, these pools do not provide inpatient health coverage directly to patients or, like insurance, make payments on behalf of specific, covered individuals, but rather directly benefit hospitals and other providers by making Medicaid funds available to compensate them for the otherwise uncompensated costs that they incur in providing medical care to the uninsured and under-insured. Making these funding pools available to hospitals and other providers to reduce their uncompensated costs advances the objective of the Medicaid program, as required by section 1115 of the Act, by making these entities more financially viable and able to continue to serve the Medicaid population. Indeed, these uncompensated care pools serve essentially the same function as Medicaid DSH payments under sections 1902(a)(13)(A)(iv) and 1923 of the Act by indirectly subsidizing the cost of treating the uninsured, while not extending Medicaid benefits to additional populations.

Consistent with our current policy of excluding patient days of individuals provided limited benefits (like family planning benefits) under a section 1115 expansion waiver from the numerator of the Medicaid fraction because the benefits they receive are too limited to be considered similar to Medicaid coverage, we believe it is also appropriate to exclude patient days for which hospitals receive payment from an uncompensated care pool or other similar funding source authorized by section 1115(a)(2). Uncompensated care pools and other funding streams provided to hospitals do not offer any medical coverage benefits directly to individuals, let alone benefits that are comparable to the panoply of benefits provided to traditional Medicaid beneficiaries under a State plan. As a result, we do not believe that the uninsured patients whose costs are partially offset by uncompensated care pools can be ''regarded'' as being eligible for Medicaid as required under section 1886(d)(5)(F)(vi) of the Act. Therefore, the patient days paid from such pools and other similar sources should not be included in the calculation of the Medicare DSH adjustment.

Similarly, we believe the days of patients who, under a section 1115 expansion waiver, receive premium assistance—that is, financial assistance that can be used to help with the purchase of health insurance from a private entity—should also be excluded from the DSH calculation. Like patients receiving only a family planning or other limited benefit from a demonstration project, premium assistance patients do not receive guaranteed health insurance coverage for inpatient hospital services. Rather, they receive money they can use to buy private health insurance that may not necessarily provide the same type of benefits traditional Medicaid beneficiaries receive. Moreover, premium assistance is usually offered on a sliding scale with relatively wealthy individuals receiving smaller subsidies and individuals with lower incomes receiving higher subsidies. As a result, individuals who receive premium assistance under an expansion waiver program may be significantly wealthier than traditional Medicaid beneficiaries. Because individuals receiving premium assistance as part of an expansion waiver do not directly receive health insurance for inpatient hospital services and may have higher incomes than traditional Medicaid beneficiaries, we do not believe the days of such patients are properly included in the numerator of the Medicaid fraction.

Recently, however, courts have decided in a series of cases (*Bethesda Health, Inc.* v. *Azar*, 980 F.3d 121 (DC Cir. 2020); Forrest General Hospital v. Azar, 926 F.3d 221 (5th Cir. 2019); *HealthAlliance Hosps., Inc.* v. *Azar*, 346 F. Supp. 3d 43 (D.D.C. 2018)) that, based on the current language of the regulations, CMS is required to count in the numerator of the Medicaid fraction patient days for which hospitals have

[938] *Portland Adventist Med. Ctr.* v. *Thompson,* 399 F.3d 1091, 1096 (9th Cir. 2005).

[939] *Cookeville Reg'l Med. Ctr.* v. *Thompson,* No. 04–1053, 2005 WL 3276219, at *4–6 (D.D.C. Oct. 28, 2005).

received payment from an uncompensated care pool authorized by a section 1115 demonstration and the days of patients who receive premium assistance under a section 1115 demonstration program. These courts have concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, that patient is ''eligible for inpatient hospital services'' within the meaning of the current regulation. Likewise, the courts have concluded that patients who receive premium assistance to pay for private insurance that covers inpatient hospital services are ''eligible for inpatient hospital services'' within the meaning of the current regulation. As discussed previously, that was not our intent when we adopted the current language of the regulation, and we continue to believe that it is not appropriate to include patient days associated with these types of expansion programs in the Medicare DSH calculation because the benefits offered under these section 1115 demonstrations are not similar to traditional Medicaid benefits and may be provided to individuals with much higher incomes.

In light of these court decisions, we believe it is appropriate to further revise our regulations to ensure that the only section 1115 days that may be counted in the numerator of the Medicaid fraction are the days of patients for whom a section 1115 waiver provides inpatient hospital insurance coverage benefits directly to that patient on that day. Medicaid provides inpatient hospital insurance benefits directly to specific individuals. Patient days associated with a section 1115 waiver program that does not similarly directly provide inpatient hospital insurance coverage to specific individuals are not comparable to the days of patients receiving traditional Medicaid benefits, and therefore, should not be counted in the numerator of the Medicaid fraction. Accordingly, we are proposing to revise the regulation at § 412.106(b)(4)(i) to state explicitly that a patient is deemed eligible for Medicaid for the purposes of the DSH calculation on a given day, and the corresponding patient day is included in the numerator of the Medicaid fraction, only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan that includes coverage for inpatient hospital care on that day or directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act. We also propose to remove § 412.106(b)(4)(ii) in its entirety as this provision would no longer be needed.

We invite comments on this proposal.

G. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system (IPPS) for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the proportion of beneficiaries who are dually eligible for Medicare and full-benefit Medicaid (''dually eligible beneficiaries'') in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401);
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676);
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048);
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543);
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979);
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240);
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439);
- FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390); and
- FY 2021 IPPS/LTCH PPS final rule (85 FR 58844 through 58847).

We have also codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154. In section V.G.15 of the preamble of this proposed rule, we are proposing to update the regulatory text at 42 CFR 412.154(f)(4) to add the phrase ''or successor website'' in order to reflect the change in the CMS website name from Hospital Compare to Care Compare.

3. Summary of Proposed Policies for the Hospital Readmissions Reduction Program

In section V.G.5 of the preamble of this proposed rule, we are proposing to adopt a cross-program measure suppression policy due to the impact of the COVID–19 public health emergency (PHE) on quality measurement and pay-for-performance programs including the Hospital Readmissions Reduction Program. In section V.G.6 of the preamble of this proposed rule, we are proposing to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) and we provide information on technical specification updates for the remaining five condition/procedure-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators beginning in fiscal year (FY) 2023. In section V.G.8 of the preamble of this proposed rule, we are proposing to use the MedPAR data to determine aggregate payments that aligns with the applicable period for FY 2022. In section V.G.9 of the preamble of this proposed rule, we are proposing the automatic adoption of the use of MedPAR data corresponding to the applicable period beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary. In section V.G.13 of the preamble of this proposed rule, we are clarifying our Extraordinary Circumstances (ECE) Policy. In section V.G.14 of the preamble of this proposed rule, we request public comment on possible future stratification of results by race and ethnicity for our condition/procedure-specific readmission measures and by expansion of standardized data collection to additional social factors, such as language preference and disability status. We are also seeking comment in that section on mechanisms of incorporating other demographic characteristics into analysis that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

We discuss these proposals in greater detail in this proposed rule.

4. Current Measures

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. However, due to the potentially substantial relationship between pneumonia and COVID–19, we are proposing to suppress temporarily the inclusion of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) in the Hospital Readmissions Reduction Program measure set for the FY 2023 applicable period in section V.G.6 of this preamble. We are also providing information on technical specification updates for the remaining five condition/procedure-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators, including the Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505), the Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515), the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891), the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330), and the Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) beginning in FY 2023.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework. We refer readers to section IX.A of this proposed rule, where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section). We also refer readers to section IX.B of this proposed rule, where we request information on potentially expanding the scope of our methodology to adjust outcomes measurement to recognize disparities in care, to include statistically estimated race and ethnicity information.

5. Proposed Flexibility for Changes That Affect Quality Measures During a Performance Period in the Hospital Readmissions Reduction Program

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had and continues to have significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 PHE impedes effective quality measurement in several ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. Measures used in the Hospital Readmissions Reduction Program need to be evaluated to determine whether their specifications need to be updated to account for new clinical guidelines, diagnoses or procedure codes, and medications that we have observed during the PHEs. Additionally, COVID–19 prevalence is not identical across the country, meaning that the medical provider community has been affected differently at different times throughout the calendar year. Under those circumstances, we remain significantly concerned that the Hospital Readmissions Reduction Program's quality measurement scores are distorted, which would result in skewed payment incentives and inequitable payments, particularly for hospitals that have treated more COVID–19 patients than others.

It is not our intention to penalize hospitals for performance on measures that are affected significantly by global events like the COVID–19 PHE. As previously discussed, the COVID–19 PHE has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including readmissions to the hospital as measured by the Hospital Readmissions Reduction Program. As a result of the PHE, hospitals could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower incentive payments in the Hospital Readmissions Reduction Program. We are concerned that regional and temporal differences in COVID–19 prevalence during the FY 2022 Hospital Readmissions Reduction Program applicable period, which includes data collected during the PHE, have directly affected hospitals' readmissions measure performance for the FY 2022 program year. Although regional and temporal differences in COVID–19 prevalence rates would not necessarily represent differences in the quality of care furnished by hospitals, they would directly affect the payment adjustments that these hospitals would receive and could result in an unfair and inequitable distribution in the assessment of penalties for excess readmissions. These inequities could be especially pronounced for hospitals that have treated a large number of COVID–19 patients.

Therefore, we are proposing to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress the use of quality measures via adjustment to the Hospital Readmissions Reduction Program's scoring methodology if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the associated ''excess readmissions'' calculations significantly. Under this proposed policy, if we determine that the suppression of a Hospital Readmissions Reduction Program measure is warranted for a Hospital Readmissions Reduction Program applicable period, we would propose to calculate the measure's rates for that program year but then suppress the use of those rates to make changes to hospitals' Medicare payments. In the Hospital Readmissions Reduction Program, this policy would have the effect of temporarily weighting the affected measure at 0% in the program's scoring methodology until adjustments are made, the affected portion of the performance period for the measure is no longer applicable to program scoring, or the measure is

removed entirely through rulemaking. We would still provide feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they are made aware of the changes in performance rates that we have observed. We would also publicly report suppressed measures' data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19.

In developing this proposed policy, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program. We believe that significant deviation in measured performance that can be reasonably attributed to the PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we believe that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 PHE, we believe that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also note that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new diseases or conditions. Finally, we believe that, as evidenced during the COVID–19 PHE, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress a Hospital Readmissions Reduction Program measure for one or more program years that overlap with the PHE for COVID–19. We are proposing to adopt these Measure Suppression Factors for use in the Hospital Readmissions Reduction Program, and for consistency, the following value-based purchasing programs: Hospital VBP Program, HAC Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We believe that these Measure Suppression Factors will help us evaluate the Hospital Readmissions Reduction Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are:

1. Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

2. Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.

3. Rapid or unprecedented changes in:

(i) Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

(ii) the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

4. Significant national shortages or rapid or unprecedented changes in: (i) Healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix.

We also considered alternatives to this proposed policy that could also fulfill our objective to not hold hospitals accountable for measure results under the Program that are distorted due to the PHE for COVID–19. As previously noted, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, CMS issued a nationwide, blanket ECE for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 PHE. This blanket ECE waived all data reporting requirements for Q1 and Q2 2020 data, including waiving the use of claims data and data collected through the CDC's web-based surveillance system for this data period, and quality data collection resumed on July 1, 2020. We considered extending this blanket ECE for Q3 and Q4 2020. This alternative would protect providers and suppliers from having their quality data used for quality scoring purposes while those data are likely to have been affected significantly by the COVID–19 PHE. However, this option would make providers' quality data collection and reporting to CMS no longer mandatory and would leave no comprehensive data available for us to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

As an alternative to the proposed quality measure suppression policy, we also considered not making any further changes to the Program and implementing it as previously specified. However, this alternative would mean assessing hospitals using quality measure data that has been significantly affected by the PHE for COVID–19. Additionally, given the geographic disparities in the COVID–19 PHE's effects, implementation of the Program as previously finalized would place hospitals in regions that were more heavily affected by the PHE in Q3 and Q4 of 2020 at a disadvantage compared to hospitals in regions that were more heavily affected during the first two quarters of CY 2020.

We view the measure suppression proposal as a necessity to ensure that the Hospital Readmissions Reduction Program does not reward or penalize hospitals based on factors that the Program's measures were not designed to accommodate. We intend for this proposed policy to provide short-term relief to hospitals when we have determined that one or more of the Measure Suppression Factors warrants the suppression of one or more of the Program's measures.

We invite public comments on this proposal for the adoption of a measure suppression policy for the Hospital Readmissions Reduction Program for the duration of the PHE for COVID–19, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy.

We are also inviting comment on whether we should consider adopting a measure suppression policy in the situation of a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress certain measures without specifically proposing to do so in rulemaking.

We also request comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also request commenters' feedback on whether we should, rather

than suppress a measure completely by assigning it a 0 percent weight, consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

6. Proposals To Address the Impact of COVID–19 on Current Hospital Readmissions Reduction Program Measures

a. Background

On March 11, 2020, the WHO publicly declared COVID–19 a pandemic. On March 13, 2020, the President declared the COVID–19 pandemic a national emergency. On April 21, 2020, July 23, 2020, October 2, 2020, and January 7, 2021, the Secretary renewed the January 31, 2020 determination that a PHE for COVID–19 exists and has existed since January 27, 2020. The Secretary may renew the PHE every 90 days until such time as the Secretary determines that a public health emergency no longer exists.

In response to the PHE for COVID–19, we have conducted analyses on the six current Hospital Readmissions Reduction Program measures to determine whether and how COVID–19 may have impacted the validity of these condition/procedure-specific readmission measures. For the reasons discussed below, we have concluded that COVID–19 has severely impacted the validity of the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) (hereafter referred to as the CMS 30-Day Pneumonia Readmission Measure (NQF #0506)), such that we cannot fairly assess this measure. The FY 2022 CMS 30-Day Pneumonia Readmission Measure (NQF #506) applicable period is July 1, 2017 through June 30, 2020. However, in the September 2020 IFC, we noted that we would except the use of any first or second quarter CY 2020 claims data from our calculation of performance for the applicable fiscal years (85 FR 54833). With this exception, the FY 2022 applicable period for this measure would only be affected by a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data from the COVID–19 PHE. Therefore, we have determined that it is not necessary to suppress this measure for the FY 2022 program year. However, given the ongoing status of the PHE and the impact of COVID–19 on this measure data, we are proposing to temporarily suppress this measure for the FY 2023 program year.

Although COVID–19 has also impacted the five remaining condition/procedure-specific measures, we have concluded that this impact is less severe overall and can be further mitigated by updating the measure specifications to exclude Medicare beneficiaries with a secondary diagnosis of COVID–19. Therefore, we are not proposing to suppress the five remaining condition/procedure-specific measures for the FY 2022 program year but are updating their specifications instead. The measures are as follows:

- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505);
- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891);
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330); and
- Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

As discussed more fully later in this section, we are modifying these five condition/procedure-specific measures to exclude COVID–19 patients from the measure denominators as technical updates to the measure specifications.

b. Proposal To Suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 Program Year

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51664 through 51666), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 24490 through 24492) for information on our policies that relate to refinement of the readmissions measures and related methodology for the current applicable conditions/procedures.

In this proposed rule, we are proposing to suppress temporarily the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for the FY 2023 program year under proposed Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease or pathogen, particularly for a novel disease or pathogen of unknown origin, due to the COVID–19 PHE. COVID–19 is caused by the SAR-CoV–2 virus, which begins when respiratory droplets containing the virus enter an individual's upper respiratory tract.[940] Pneumonia has been identified as a typical characteristic of individuals infected with COVID–19,[941] and our analysis based on data from CY 2020 shows that a substantial portion of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) cohort includes admissions with a COVID–19 diagnosis. In addition, almost all of the admissions with a COVID–19 diagnosis have a principal diagnosis of sepsis; observed mortality rates for these admissions are extremely high and are substantially higher than admissions without a COVID–19 diagnosis. We are concerned that these higher mortality rates may also potentially distort readmissions data for the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) cohort. Based on the currently available data for this measure, there is a high percentage of Medicare beneficiaries with a secondary diagnosis of COVID–19 in the measure cohort during CY 2020.

In accordance with the previously discussed measure suppression policy, we would weight the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) at zero percent in the Hospital Readmissions Reduction Program payment methodology such that claims data for this measure would not be used to assess that hospital's performance. Additionally, we would continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. We would also continue to provide feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that are observed and to inform quality improvement activities.

As previously discussed, the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) FY 2022 applicable period is July 1, 2017 through June 30, 2020.

[940] CDC. ''How COVID–19 Spreads''. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[941] CDC. ''Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID–19)''. Updated February 16, 2021. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html.*

However, in the September 2020 IFC, we noted that we would not use any first or second quarter CY 2020 claims data to assess performance for the applicable fiscal years (85 FR 54833). With this exception, the FY 2022 applicable period for this measure would only be affected by a shortened performance period (July 1, 2017 through December 1, 2019) that does not use data impacted by the COVID–19 PHE. Therefore, we have decided that it is not necessary to suppress this measure for the FY 2022 program year. However, given the ongoing status of the PHE and the impact of COVID–19 on this measure's data, we are proposing to temporarily suppress this measure for the FY 2023 program year.

Our analysis of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) claims data showed that a higher proportion of patients had a secondary diagnosis of COVID–19 than other readmission measures and that these patients have a higher risk of mortality than the remainder of the admissions in the pneumonia measure cohort.

Table V.G-2: Observed Readmissions Rate for Admissions with/without Secondary Diagnosis of COVID-19 Present on Admission (POA)

	Number of Admissions	Number of Readmissions	Observed 30-Day Readmissions Rate
Admissions with Secondary Diagnosis of COVID-19 POA	6,421	793	12.4%
Admissions without a Diagnosis of COVID-19	59,435	9,389	15.8%

Table V.G-1: Percent of COVID-19 Diagnoses in Readmission Measure Cohorts, March – September 2020

Readmission Measure Cohort	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020
Pneumonia	4.5	13.3	11.2	6.7	15.6	14.5	9.8
COPD	0.2	0.3	0.2	0.2	0.4	0.5	0.4
AMI	0.1	0.5	0.6	0.5	1.0	1.1	0.8
HF	0.1	0.4	0.6	0.6	0.7	0.8	0.7
THA/TKA	0.0	0.3	0.1	0.1	0.1	0.1	0.1
CABG	0.0	0.1	0.2	0.2	0.4	0.4	0.3

Data from September 2020 showed that although admission volumes for this cohort were substantially lower compared to admission volumes in September 2019, the observed readmission rates were statistically significantly higher compared to the observed readmission rates for this cohort during the same period in 2019.

Our analyses performed with available data demonstrated that COVID–19 patients captured in the pneumonia readmission measure cohort likely represent a distinct, severely ill group of patients for whom it may be difficult to adequately ascertain appropriate risk adjustment. We want to ensure that the measure reflects care provided by the hospital to Medicare beneficiaries admitted with pneumonia and we are concerned that excluding a significant proportion of all eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across hospitals over time. Suppressing this measure for the FY 2023 program year would address this concern.

As part of our analysis, we also evaluated the impact of suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) on hospital eligibility, program calculations, and payment for the FY 2023 program year. We note that we used data from the most recently completed performance period, FY 2021, to simulate removal of the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) as compared to the baseline data.[942] We found that the suppression of the CMS 30-Day Pneumonia Readmission

[942] We note that, for purposes of this analysis, we removed the pneumonia readmission measure from program results calculated using a 29-month performance period.

Measure (NQF #0506) resulted in about a 1 percent decrease in eligibility for hospitals with at least 25 eligible discharges for any of the readmission measures under the Hospital Readmissions Reduction Program; the number of hospitals receiving a payment reduction was reduced by 5.17 percent; the penalty as a share of payments, or the weighted average payment reduction decreased by .13 percentage points; and the estimated Medicare savings decreased by 22.20%. Therefore, we believe that suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) measure would have a minimal negative impact on eligibility for the Hospital Readmissions Reduction Program, and the number of hospitals receiving payment reductions. Although we note that suppressing the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) measure would have larger impacts on the weighted average payment reduction and the estimated Medicare savings under the Hospital Readmissions Reduction Program, the reduction in penalty as a share of payments and estimated Medicare savings are expected based on the program methodology in which each measure contributes to the payment reduction additively, increasing the size of the payment reduction.

We are seeking comments on our proposal to suppress the current CMS 30-Day Pneumonia Readmission Measure (NQF #0506) for FY 2023.

c. Technical Measure Specification Update To Exclude COVID–19 Diagnosed Patients From All Other Condition/Procedure-Specific Readmission Measures Beginning With FY 2023

In the FY 2015 IPPS/LTCH final rule, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital Readmissions Reduction Program (79 FR 50039). We reiterated this policy in the FY 2020 IPPS/LTCH final rule, stating our continued belief that the subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385). Due to the impact of the COVID–19 PHE on the measures used in the Hospital Readmissions Reduction Program, as described previously, we are updating these five condition/procedure-specific readmission measures to exclude COVID–19 diagnosed patients from the measure denominators. This technical update will modify these five condition/procedure-specific readmission measures to exclude certain ICD–10 Codes that represent patients with a secondary diagnosis of COVID–19 from the measure denominators, but will retain the measures in the program.

We believe that excluding COVID–19 patients from the measure denominator will ensure that these five condition/procedure-specific readmission measures continue to account for readmissions as intended and meet the goals of the Hospital Readmissions Reduction Program. Additional resources about the current measure technical specifications and methodology for the Hospital Technical specification of the current readmission measures are provided at our website in the Measure Methodology Reports (available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*). Readmissions Reduction Program are on the Resources web page of the QualityNet website (available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412995*).

7. Automatic Adoption of Applicable Periods for FY 2023 and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53375) for discussion of our previously finalized policy for defining ''applicable period''. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41434 through 41435) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42387), we finalized the ''applicable period'' consistent with the definition specified at 42 CFR 412.152, to calculate the readmission payment adjustment factor for FY 2022 as the 3-year time period of July 1, 2017 through June 30, 2020.[943]

The ''applicable period'' is the 3-year period from which data are being collected in order to calculate excess readmission ratios (ERRs) and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The ''applicable period'' for dually eligible beneficiaries is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

In order to provide greater certainty around future applicable periods for the Hospital Readmissions Reduction Program, in the FY 2021 IPPS/LTCH final rule (85 FR 58846), we finalized the automatic adoption of applicable periods for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program. We remind readers that, beginning in FY 2023, the applicable period for the Hospital Readmissions Reduction Program will be the 3-year period beginning 1 year advanced from the previous program fiscal year's start of the applicable period. Under this policy, for all subsequent years, we will advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. Similarly, the applicable period for dual eligibility will continue to correspond to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58845 through 58846) for a more detailed discussion of this topic. We are not proposing any updates to this policy in this proposed rule.

8. Proposal To Identify Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2022

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2022 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of

[943] Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for program calculation purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE.

specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring on or after October 1, 2015 (FY 2016) began reporting under the ICD–10–CM and ICD–10–PCS code sets as opposed to the previous ICD–9–CM code set.

We identify Medicare fee-for-service (FFS) claims that meet the criteria as previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. This means that claims paid for under Medicare Part C (Medicare Advantage) are not included in this calculation. This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2022, we are proposing to continue to exclude admissions for patients enrolled in Medicare Advantage (MA), as identified in the Medicare Enrollment Database.

In this proposed rule, for FY 2022, we are proposing to determine aggregate payments for excess readmissions, and aggregate payments for all discharges using data from MedPAR claims with discharge dates that align with the FY 2022 applicable period.[944] As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we will determine the neutrality modifier using the most recently available full year of MedPAR data. However, we note that, for the purpose of modeling the proposed FY 2022 readmissions payment adjustment factors for this proposed rule, we are using the proportion of dually eligible beneficiaries, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2021 Hospital Readmissions Reduction Program applicable period (July 1, 2016 through June 30, 2019). For the FY 2022 program year, applicable hospitals will have the opportunity to review and correct calculations based on the FY 2022 applicable period of July 1, 2017 to December 1, 2019, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

In this proposed rule, we are proposing to continue to use MedPAR data corresponding to the applicable period for identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions for the Hospital Readmissions Reduction Program. We are proposing to use the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source.

We welcome public comment on this proposal to identify aggregate payments for each condition/procedure and all discharges for the FY 2022 applicable period using corresponding MedPAR data.

9. Proposed Automatic Adoption of the Use of MedPAR Data Corresponding to the Applicable Period Beginning in FY 2023

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53387 through 53390) for discussion of our previously finalized policy for the use of MedPAR claims data as our data source for determining aggregate payments for each condition/procedure and aggregate payments for all discharges during applicable periods. Most recently, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58846), we finalized our policy on the continued use of the MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations for the FY 2021 applicable period. We also finalized our policy to use the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source to identify discharges within the FY 2021 applicable period during that fiscal year. Similarly, in section V.G.8 of this proposed rule, we are proposing to use MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations for the FY 2022 applicable period, and to use the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source.

We continue to believe that the use of MedPAR claims data is the appropriate source for identifying aggregate payments for each condition/procedure and all discharges during the corresponding applicable period for the Hospital Readmissions Reduction Program. In order to provide greater certainty around future applicable periods for the Hospital Readmissions Reduction Program, in the FY 2021 IPPS/LTCH final rule (85 FR 58845 through 58846), we finalized the automatic adoption of applicable periods for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program. Under this policy, the 3-year applicable period will automatically advance by 1 year beginning in FY 2023. Because the MedPAR data used for the Hospital Readmissions Reduction Program calculations corresponds to the applicable period, we believe that the automatic adoption of the use of MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations each year will similarly streamline the process and provide additional clarity and consistency to the program.

Therefore, we are proposing to automatically adopt the use of MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations for FY 2023 and all subsequent program years. We propose that, beginning in FY 2023, the MedPAR data used to calculate aggregate payments for each condition/procedure and for all discharges will be the 3-year period beginning 1 year advanced from the previous program fiscal year's MedPAR data corresponding to the applicable period for Hospital Readmissions Reduction Program calculations. Under this proposal, for all subsequent years, we would advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. We also propose to automatically adopt the use of the update of the MedPAR file for each Federal FY, which is updated 6 months after the end of each Federal FY within the applicable period, as our data source, and to similarly advance this by 1 year from the previous program fiscal year.

We welcome public comment on this proposal.

10. Calculation of Payment Adjustment Factors for FY 2022

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226),

[944] Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for scoring purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments would be adjusted to July 1, 2017 through December 1, 2019. Further information will be found in the FY 2022 Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hrrp/reports* that is anticipated to become available in August 2021.

section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups, based on the proportion of dually eligible beneficiaries served by each hospital, in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019. Section 1886(q)(3)(D) also states that this methodology could be replaced through the application of subclause (E)(i), which states that the Secretary may take into account the studies conducted and the recommendations made by the reports required by section 2(d)(1) of the IMPACT Act of 2014 (Pub. L. 113–185; 42 U.S.C. 1395 note) with respect to risk adjustment methodologies. On June 29, 2020,[945] the second Report to Congress by the Department's Office of the Assistant Secretary for Planning and Evaluation (ASPE) on social risk and Medicare's value-based purchasing programs came out. We are continuing our review of these recommendations and will address them as appropriate in future rulemaking.

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. We are not proposing any changes to this payment adjustment calculation methodology for FY 2022 in this proposed rule.

11. Calculation of Payment Adjustment for FY 2022

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) The ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of aggregate payments for excess readmissions to aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at 42 CFR 412.154(c)(1) and the floor adjustment factor is codified at 42 CFR 412.154(c)(2). Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at 42 CFR 412.154(c)(2), for FY 2022, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2022, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

For additional information on the FY 2022 payment calculation, we refer readers to the Hospital Readmissions Reduction Program information and resources available on our QualityNet website. We are not proposing any changes to our calculation of payment methodology in this proposed rule.

12. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital Readmissions Reduction Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule for details (85 FR 86193 through 86236).

13. Extraordinary Circumstance Exception (ECE) Policy for the Hospital Readmissions Reduction Program

a. Background

(1) Previously Established Extraordinary Circumstance Exception (ECE) Policy Under the Hospital Readmissions Reduction Program

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38239 through 38240) for discussion of our Extraordinary Circumstances Exception (ECE) policy. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49543), we adopted an ECE policy for the Hospital Readmissions Reduction Program, which recognized that there may be periods of time during which a hospital is not able to submit data (from which readmission measures data are derived) in an accurate or timely fashion due to an extraordinary circumstance beyond its control. When adopting this policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's excess readmission ratios for the applicable performance period. By minimizing the data excluded from the program, the proposed policy enabled affected hospitals to continue to participate in the Hospital Readmissions Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital Readmissions Reduction Program. We further observed that section 1886(q)(5)(D) of the Act permits the Secretary to determine the applicable period for readmissions data collection, and we interpreted the statute to allow us to determine that the period not include times when hospitals may encounter extraordinary circumstances. This policy was similar to the ECE policy for the Hospital Inpatient Quality Reporting (IQR) Program, as initially adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651) and modified in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277). We also considered how best to align an extraordinary circumstance exception policy for the Hospital Readmissions Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital Value-Based Purchasing (VBP) Program, to the extent feasible.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38239), we modified the requirements for the Hospital Readmissions Reduction Program ECE policy to further align with the processes used by other quality reporting and VBP programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

(2) Extraordinary Circumstance Exception (ECE) Granted in Response to the COVID–19 Public Health Emergency

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based

[945] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program.'' March 2020. Available at: *https://aspe.hhs.gov/system/files/pdf/263676/Second-IMPACT-SES-Report-to-Congress.pdf.*

purchasing programs.[946] Specifically, we announced that we were excluding data for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and VBP program.[947] For the Hospital Readmissions Reduction Program, we stated that qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the readmission measures.

(3) Updated Application of the ECE Granted in Response to COVID–19

On September 2, 2020, we published the Interim Final Rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the PHE for COVID–19, for the Hospital Readmissions Reduction Program and several other quality reporting programs (85 FR 54827 through 54838).

In the IFC, we updated the previously announced application of our ECE policy for the Hospital Readmissions Reduction Program (85 FR 54832 through 54833) to the COVID–19 PHE to exclude any data submitted regarding care provided during the first and second quarters of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024. We expressed concern that excess readmission ratios calculated using excepted claims data could affect the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19, and therefore may not provide a nationally comparable assessment of performance in keeping with the program goal of national comparison.

In the IFC, we welcomed public comments on our policy to exclude any data submitted regarding care provided during first and second quarter of CY 2020 from our calculation of performance for FY 2022, FY 2023, and FY 2024. We will respond to those public comments in the FY 2022 IPPS/LTCH PPS final rule.

In the September 2, 2020 IFC, we also announced that if, due to ECEs related to the COVID–19 PHE, we do not have enough data to reliably measure national performance, we may propose to not assess hospitals based on such limited data or make temporary payment adjustments to facilities under the Hospital Readmissions Reduction Program for the affected program year. We stated that, if circumstances warranted, we could propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. We also stated that, in the interest of time and transparency, we would provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memos, emails, and notices on the public QualityNet website (*https://www.qualitynet.cms.gov/*).[948]

b. General Clarifications to Hospital Readmissions Reduction Program ECE Policy

After the nationwide ECE granted in response to the COVID–19 PHE ended, we received several requests from hospitals for individual ECEs under the Hospital Readmissions Reduction Program, due to extraordinary circumstances resulting from the continuing impact of the PHE. In this proposed rule, we would like to clarify our ECE policy to highlight that an ECE granted under the Hospital Readmissions Reduction Program would exclude claims data during the corresponding ECE period. Although we have considered the feasibility and implications of excluding data under the ECE policy for the Hospital Readmissions Reduction Program, we have never specified the types of data that would be excluded under an ECE granted to an individual hospital. Considering that the Hospital Readmissions Reduction Program only uses claims data, we would like to clarify our ECE policy to specify that claims data will be excluded from calculations of measure performance under an approved ECE for the Hospital Readmissions Reduction Program.

The FY 2016 IPPS/LTCH final rule specifies that we may waive reporting requirements for the Hospital Readmissions Reduction Program in response to ECE requests, in alignment with the Hospital Inpatient Quality Reporting (IQR) policy (80 FR 49542). Although the Hospital Readmissions Reduction Program and the Hospital IQR Program use different sources of data and have different requirements depending on the type of measure, the ECE policy applies to both programs. Therefore, in this proposed rule we clarify that although an approved ECE for the Hospital Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, we are not proposing to waive the data submission requirements of a hospital for claims data. For example, for claims data, we require a hospital to submit claims to receive payments for the services they provided to patients. Although an individual ECE approval under the Hospital Readmissions Reduction Program would except data submitted by a hospital from Hospital Readmissions Reduction Program calculations, a hospital would still need to submit its claims in order to receive reimbursement outside the scope of the Hospital Readmissions Reduction Program for services provided.

We have also received a few requests from hospitals for ECEs under the Hospital Readmissions Reduction Program, in which the hospitals requested an exception from the Hospital Readmissions Reduction Program payment reduction. The ECE policy for the Hospital Readmissions Reduction Program is intended to provide relief for a hospital that has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the hospital's control by excepting data from the period during which performance was impacted. The hospital would still be evaluated for the remainder of the applicable period during which performance was not impacted. The ECE policy is not intended to extend to payment reductions. Therefore, we would like to clarify that, although an approved ECE for the Hospital

[946] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting*.

[947] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*.

[948] We note that the QualityNet website (previously at *QualityNet.org*) has transitioned to a *QualityNet.cms.gov*.

Readmissions Reduction Program would exclude excepted data from Hospital Readmissions Reduction Program payment reduction calculations, it does not exempt hospitals from payment reductions under the Hospital Readmissions Reduction Program. Instead of relying upon our ECE policy, we are relying upon our authority under subsection 1886(q)(5)(A)(i) of the Act to determine the scope of ''applicable conditions'', including the Secretary's authority to utilize his own criteria to select measures to be used to calculate the excess readmission measure.

c. Clarification of the Impact of ECE Excluded Data for the Hospital Readmissions Reduction Program

In this proposed rule, we clarify the impact of data which has been excluded from the Hospital Readmissions Reduction Program due to the nationwide ECE that was granted in response to COVID–19 on upcoming Hospital Readmissions Reduction Program calculations. In order to determine and evaluate what kind of impact the nationwide ECE might have on the Hospital Readmissions Reduction Program, we conducted analyses to simulate the impact of an altered performance period on program eligibility and the resulting payment impacts to hospitals using pre-COVID–19 data from the FY 2020 Hospital Readmissions Reduction Program year. This analysis was intended to evaluate what patterns we might observe in Hospital Readmissions Reduction Program eligibility and payment as a result of excluding 6 months of data due to the ECE granted in response to the PHE for COVID–19. Our analysis found that there would be a minimal impact on hospitals when 6 months of data are removed from Hospital Readmissions Reduction Program calculations. We are performing additional analyses as CY 2020 data becomes available, and we will provide updated analyses as necessary when it becomes available.

Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, due to the first and second quarter CY 2020 claims exception period and the 30-day window to identify readmissions, the period for calculating ERRs would be adjusted to July 1, 2017 through December 1, 2019. The period for calculating DRG payments would similarly be adjusted to July 1, 2017 through December 1, 2019 to align with the period to calculate ERRs. We would also note that CY 2019 data would be used to calculate the Neutrality Modifier, as that would be the most recent full year of data (since Q1 and Q2 CY 2020 data are excluded from FY 2020 data under the nationwide ECE). Finally, we note that each of the readmission measures uses claims data for the 12 months prior to the index hospitalization as well as index hospitalization claims for risk adjustment (76 FR 51672). Due to the nationwide ECE that was granted in response to the COVID–19 PHE, the condition/procedure-specific measures will use less than 12 months of data for risk adjustment for admissions between July 1, 2020 and June 30, 2021 during the FY 2023 applicable period. For example, if not for the COVID–19 PHE and subsequent nationwide ECE, an admission on July 1, 2020 would have included 12 months of prior claims data—a lookback period of July 2, 2019 through June 30, 2020—for risk adjustment. Because claims data from January 1, 2020 through June 30, 2020 are excluded under the nationwide ECE, an admission on July 1, 2020 will have a shorter lookback period of July 2, 2019 through December 31, 2019. Comorbidities from the index admission will continue to be used for all admissions.

In the FY 2020 IPPS/LTCH PPS final rule, we finalized our policy to adopt a subregulatory process to make nonsubstantive updates to payment adjustment factor components to facilitate the program's operation when minor changes are required, but do not substantively impact the program's previously finalized policies (84 FR 42385 through 42387). Based on our analysis showing that there would be a minimal impact when 6 months of data are removed from Hospital Readmissions Reduction Program calculations, we believe that these updates to payment adjustment factor components are nonsubstantive and do not substantially impact the Hospital Readmissions Reduction Program's previously finalized policies. Therefore, we would like to clarify that the impact of the two quarters of data that were excluded from the Hospital Readmissions Reduction Program due to the nationwide ECE that was granted in response to COVID–19 on payment adjustment factor components will be addressed through the subregulatory process. For more details on these subregulatory updates, we refer readers to the Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hrrp/reports.*

14. Request for Public Comment on Possible Future Stratification of Results by Race and Ethnicity for Condition/Procedure-Specific Readmission Measures

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[949] As described in section IX.B of this proposed rule, in response to statute and policy reports from the Assistant Secretary for Planning and Evaluation (ASPE) of HHS and the National Academies of Science, Engineering and Medicine to better account for social risk factors in the Medicare program,[950] we have created two complementary methods to calculate disparities in condition/procedure-specific readmission measures (the CMS Disparity Methods). The first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of those differences, or disparities, across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for subgroups of patients across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. We refer readers to the technical report describing the CMS Disparity Methods in detail as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407) and the posted Disparity Methods Updates and Specifications Report posted on the QualityNet website. The CMS Disparity Methods have thus far focused on dual eligibility, a proxy for social risk factors, as the main stratification variable for reporting

[949] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[950] ASPE, Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs (2016), *https://aspe.hhs.gov/system/files/pdf/253971/ASPESESRTCfull.pdf.* For more information, see National Academies of Sciences, Engineering, and Medicine, Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors (2016), *https://doi.org/10.17226/21858.* See also, Improving Medicare Post-Acute Care Transformation Act of 2014 (2014), *https://www.govinfo.gov/content/pkg/BILLS-113hr4994enr/pdf/BILLS-113hr4994enr.pdf.*

disparity results. These stratified data are provided in confidential Hospital Specific Reports (HSRs) for six condition/procedure-specific readmission measures and not publicly reported at this time. The disparity methods were designed to accommodate additional types of stratification variables, such as race and ethnicity, language preference, and disability status.

As described in section IX.B.3 of this proposed rule, we are seeking comment on potentially expanding our methods for stratified reporting of the Disparity Methods to better illuminate social disparities in populations served by Medicare-participating hospitals. As described in section IX.B.3 of the proposed rule, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications. We are, in particular, exploring the significance of racial and ethnic inequities, as well as other social factors such as language preference and disability status, in outcomes in the Hospital Readmissions Reduction Program.[951] Expanding the disparity methods to include stratified results by both dual eligibility and race and ethnicity, as well as language preference and disability status, may enable a more comprehensive assessment of health equity and support initiatives to close the equity gap. We believe that hospitals will be able to use the results from the disparity methods to identify and develop strategies to promote health equity.

More specifically, we are seeking comment on expanding our efforts to provide hospital-level results of both the Within- and Across-Hospital Disparity Methods, as described in section IX.B.3 of this proposed rule, using indirectly estimated race and ethnicity, as well as additional social factors, such as language preference and disability status. Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[952] Imputed data are most commonly used at the population level, where aggregated results form a more accurate description of the population than existing, imperfect data sets. Section IX.B.3 of this proposed rule also summarizes the existing challenges in accurately determining race and ethnicity in our administrative data, the need for using advanced statistical methods for indirectly estimating race and ethnicity, and the previous algorithms developed to indirectly estimate race and ethnicity in our data. The expanded methods would be reported at the hospital-level, and provided to hospitals in confidential HSRs for six condition/procedure-specific readmission measures, stratified by both dual eligibility and race/ethnicity: (1) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505); (2) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515); (3) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891); (4) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330); (5) Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551); and (6) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization (NQF #0506), for groups where results are technically feasible, adequately representative, and statistically reliable.[953]

To allow stakeholders an opportunity to become more familiar with, and gain comfort in interpreting stratified results using indirect estimation of race and ethnicity as described in section IX.B.3 of this proposed rule, hospitals would receive *confidential HSRs* containing results for the six condition/procedure-specific readmission measures, stratified by both dual eligibility and race/ethnicity in Spring 2022, prior to anticipated future publication of results in Spring 2023. Any proposal to publicly display stratified quality measure data for these six condition/procedure-specific readmission measures as previously described on the Care Compare website, or expand stratified reporting to additional social risk factors, would be made through future rulemaking.

We invite public comment on the following: (1) The possibility of confidentially reporting in HSRs stratified results using indirectly estimated race and ethnicity in addition to the currently reported results stratified using dual eligibility, for the six condition/procedure-specific readmission measures, and by expansion of standardized data collection to additional social factors, such as language preference and disability status; (2) the possibility of publicly reporting stratified results using both indirectly estimated race and ethnicity, and dual eligibility, publicly on Care Compare, after at least one year of confidential reporting and further rulemaking, for the six condition/procedure-specific measures; and (3) on possible mechanisms of incorporating other demographic characteristics into analysis that address and advance health equity, such as the potential to include administrative and self-reported data to measure co-occurring disability status.

15. Proposed Regulatory Updates (42 CFR 412.154)

We are proposing to update the references to CMS resources in regulation text. First, we note that we renamed our Hospital Compare website. It is now referred to as Care Compare and is available at: *https://www.medicare.gov/care-compare*. We are proposing to revise our regulations for the Hospital Readmissions Reduction Program at 42 CFR 412.154(f)(4) to reflect the new website name. We propose to amend CFR 412.154(f)(4), by adding the phrase ''or successor website'' so that the text reads ''Hospital Compare website or successor website.'' [954]

We invite public comment on our proposal.

H. Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based

[951] For example, see the RIT Race Code, available at *https://www.resdac.org/cms-data/variables/research-triangle-institute-rti-race-code. See also,* Health Serv Res. 2019 Feb; 54(1):13–23. doi: 10.1111/1475–6773.13099. Epub 2018 Dec 3.

[952] IOM. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press.

[953] Although we are proposing to suppress the CMS 30-Day Pneumonia Readmission Measure (NQF #0506) in section V.G.6 of this proposed rule, we note that the measure is not being proposed for removal and is therefore still considered one of the six condition/procedure-specific readmission measures included in the Hospital Readmissions Reduction Program.

[954] While the statute refers to Hospital Compare, the name has been changed to Care Compare. Now called Care Compare, the website continues to serve the purpose of displaying quality data submitted for the Hospital Readmissions Reduction Program.

incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

1. Proposed Flexibilities for the Hospital VBP Program in Response to the Public Health Emergency (PHE) Due to COVID–19

a. Proposed Measure Suppression Policy for the Duration of the PHE for COVID–19

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating hospitals' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE has impeded effective quality measurement in many ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. Measures used in the Hospital VBP Program need to be evaluated to determine whether their specifications need to be updated to account for new clinical guidelines, diagnosis or procedure codes, and medication changes that we have observed during the PHE. Additionally, because COVID–19 prevalence is not consistent across the country, hospitals located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we remain significantly concerned that Hospital VBP Program quality measure scores that are calculated using data submitted during the PHE for COVID–19 are distorted and will result in skewed payment incentives and inequitable payments, particularly for hospitals that have treated more COVID–19 patients than others.

It is not our intention to penalize hospitals based on measure scores that we believe are distorted by the COVID–19 PHE and, thus, not reflective of the quality of care that the measures in the Hospital VBP Program were designed to assess. As previously discussed, the COVID–19 PHE has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those made on clinical topics covered by the Hospital VBP Program's measures. As a result of the COVID–19 PHE, hospitals could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower incentive payments in the Hospital VBP Program. We are also concerned that regional differences in COVID–19 prevalence during the performance periods for the FY 2022 and FY 2023 Hospital VBP Programs, which include CY 2020 data, have directly affected hospitals' measure scores for the FY 2022 and FY 2023 Hospital VBP program years. Although these regional differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by hospitals, they directly affect the value-based incentive payments that these hospitals are eligible to receive and could result in an unfair and inequitable distribution of those incentives. These inequities could be especially pronounced for hospitals that have treated a large number of COVID–19 patients.

Therefore, we are proposing to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress the use of data for a number of measures if we determine that circumstances caused by the COVID–19 PHE have affected those measures and the resulting Total Performance Scores significantly. We are also proposing, as described more fully in section V.H.1.b. of this rule, to suppress all of the measures in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction Domains for the FY 2022 program year because we have determined that circumstances caused by the COVID–19 PHE have affected those measures significantly, and to adopt a special scoring and payment rule for that program year. Under this special rule for FY 2022, which we would codify in our regulations at § 412.168, we would calculate measure rates for all measures, including the measures we are proposing to suppress, but would only calculate achievement and improvement scores for the measures in the Clinical Outcomes Domain, which we are not proposing to suppress. We would also calculate domain scores for the Clinical Outcomes Domain but because that domain is only weighted at 25 percent of the TPS and we would have no other domain scores, we would not calculate total performance scores (TPSs) for hospitals. Finally, we would reduce each hospital's base-operating DRG payment amount by 2 percent, as required under section 1886(o)(7)(B) of the Act, but because no hospital would receive a TPS for FY 2022, we would assign to each hospital a value-based incentive payment percentage that results in a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG payment amount. The net result of these payment adjustments would be neutral for hospitals. That is, a hospital's base operating DRG payment amount would remain unchanged for FY 2022.

We would still provide confidential feedback reports to hospitals on their FY 2022 measure rates on all measures to ensure that they are made aware of the changes in performance rates that we have observed. We would also publicly report Q3 and Q4 2020 data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19. We note that, due to operational complications associated with extended deadlines for Q3 2020 data submissions for the HCAHPS and HAI measures granted in response to the system issues as well as the proposed changes in the FY 2022 scoring methodology,[955] and in order to allow enough time for the appropriate notice and comment period process, we may not be able to provide hospitals with the feedback reports for FY 2022 until after August 1, 2021. We intend to provide hospitals with these feedback reports for FY 2022 as soon as possible and estimate that we will be able to provide reports before the end of 2021.

For the FY 2023 program year, we are proposing to suppress only one measure, MORT–30–PN because we have determined that circumstances caused by the COVID–19 PHE have affected this measure significantly, but we are not proposing to adopt a special scoring and payment rule for that program year. Instead, the scoring and

[955] All Programs (IQR, OQR, PCH, Validation, VBP, eCQM, HACRP, ESRD QIP) Subject: Q3 2020 Data Submission Deadline Extension for Certain Medicare Quality Reporting and Value-Based Purchasing Programs, available at: *https://www.cms.gov/files/document/2020-12-inpatient-quarter-3-2020-extension-listserve-final.pdf.*

payment rules we previously adopted at 42 CFR 412.160–412.165 would apply. The FY 2024 and FY 2025 program years also use CY 2020 data, but we are not proposing to suppress the MORT–30–PN measure in the FY 2024 and FY 2025 program years at this time. We will continue to analyze this data and will address suppression of MORT–30–PN for additional program years in future rulemaking.

In developing this measure suppression proposal, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in the Hospital VBP Program. We believe that significant deviation in measured performance that can be reasonably attributed to the PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we believe that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 pandemic, we believe that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols, may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also note that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we believe that, as evidenced during the COVID–19 pandemic, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress a Hospital VBP Program measure for one or more program years where the baseline or performance period of the measure overlaps with the PHE for COVID–19. We are proposing to adopt these Measure Suppression Factors for use in the Hospital VBP Program and, for consistency, the following other value-based purchasing programs: Hospital Readmissions Reduction Program, HAC Reduction Program, and Skilled Nursing Facility Value-Based Purchasing Program. We believe that these Measure Suppression Factors will help us evaluate the Hospital VBP Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are:

5. Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

6. Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.

7. Rapid or unprecedented changes in:

(iii) Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

(iv) the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

8. Significant national shortages or rapid or unprecedented changes in: (i) Healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix.

We also considered alternatives to this proposed policy that could fulfill our objective to not penalize hospitals for measure results that are distorted due to the PHE for COVID–19. As previously noted, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, CMS issued a nationwide, blanket Extraordinary Circumstances Exception (ECE) for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 PHE. This blanket ECE excepted data reporting requirements for Q1 and Q2 2020 data, including excepting the use of claims data, HCAHPS survey data, and data collected through the CDC's web-based surveillance system for this data period. Quality data collection resumed on July 1, 2020. We considered extending this blanket ECE for Q3 and Q4 2020. This alternative would have protected hospitals from having their quality data used for quality scoring purposes if those data were affected significantly by the COVID–19 PHE. However, this option would have made hospital quality data collection and reporting to CMS no longer mandatory and would have left us with no comprehensive data available for use in providing confidential performance feedback to hospitals or monitoring for purposes of deciding whether programmatic changes are necessary to adequately respond to the PHE.

As an alternative to the proposed quality measure suppression policy, we also considered not suppressing any measures under the Hospital VBP Program. However, this alternative would mean assessing hospitals using quality measure data that has been significantly affected by the COVID–19 PHE. Additionally, given the geographic disparities in the COVID–19 PHE's effects, we believe that if we do not adopt a policy to suppress measures that have been significantly affected by the PHE for COVID–19, hospitals in regions that are more heavily impacted by the COVID–19 PHE will be at a disadvantage when compared to hospitals in regions that are either not as heavily impacted, or are heavily impacted at a different point in the pandemic.

We view the measure suppression proposal as a necessity to ensure that the Hospital VBP Program does not reward or penalize hospitals based on circumstances caused by the PHE for COVID–19 that the Program's measures were not designed to accommodate. We intend for this proposed policy to provide short-term relief to hospitals when we have determined that one or more of the Measure Suppression Factors warrants the suppression of one or more of the Program's measures.

We invite public comment on this proposal for the adoption of a measure suppression policy for the Hospital VBP Program for the duration of the PHE for COVID–19, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy.

We are also inviting comment on whether we should consider adopting a measure suppression policy in the situation of a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress certain measures without specifically proposing to do so in rulemaking. We also request comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also request commenters' feedback on

whether we should, rather than suppress a measure completely for scoring and payment purposes, consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

b. Proposals To Suppress Specific Measures for the FY 2022 or FY 2023 Program Year

(1) Background

We have conducted analyses on all Hospital VBP Program measures with the exception of the CMS PSI 90 measure to determine whether and how COVID–19 has impacted the validity of these measures. Our findings from these analyses are discussed in this proposed rule. We did not conduct an analysis to determine the impact of COVID–19 on the CMS PSI 90 measure performance because the CMS PSI 90 measure would not be included in TPS calculations until FY 2023, and we are proposing to remove this measure from the Hospital VBP Program beginning with FY 2023. Based on those analyses, which are discussed in more detail in this proposed rule, we are proposing to suppress the following measures for the FY 2022 program year:

- Hospital Consumer Assessment of Healthcare Provides and Systems (HCAHPS) (NQF #0166)
- Medicare Spending Per Beneficiary—Hospital (NQF #2158)
- National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
- National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
- American College of Surgeons—Centers for Disease Control and Prevention Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcomes Measure (NQF #1716)
- National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717)

We are additionally proposing to suppress the Hospital 30-Day, All Cause, Risk Standardized Mortality Rate Following Pneumonia (PN) Hospitalization measure (NQF #0468) (MORT–30–PN) for the FY 2023 program year. Our proposals are described in more detail in this proposed rule.

(2) Proposal To Suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (NQF #0166) for the FY 2022 Hospital VBP Program Year

We are proposing to suppress the HCAHPS measure for the FY 2022 program year under proposed Measure Suppression Factor 1, significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse as compared to historical performance during the immediately preceding program years. We would calculate hospitals' HCAHPS measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Additionally, because the HCAHPS measure is the only measure included in the Person and Family Engagement domain, we would not calculate hospitals' FY 2022 domain scores for the Person and Family Engagement domain. Participating hospitals would continue to report the measure's data to CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to hospitals as part of program activities to allow hospitals to track the changes in performance rates that we observe. We also intend to publicly report 2020 Q3 and Q4 2020 measure rate data where feasible and appropriately caveated.

Based on our analysis of HCAHPS data from Q1 2018 to Q3 2020, we have observed a notable decline in hospital-level HCAHPS scores. This decline is associated with the COVID–19 PHE in 2020. HCAHPS measure results are publicly reported as ''top-box,'' ''bottom-box,'' and ''middle-box'' scores, with ''top-box'' being the most positive response to HCAHPS Survey items.[956]

In order to detect the possible impact of the COVID–19 PHE on patients' experience of hospital care, we conducted an ''apples-to-apples'' analysis in which we compared hospitals' HCAHPS measure top-box scores for each quarter between Q1 2019 and Q3 2020 to their top-box scores for each of the same quarters one year earlier. For example, scores from Q1 2019 were compared to scores from Q1 2018, and scores from Q3 2020 (the most recent data available) were compared to scores from Q3 2019. The pre-COVID–19 quarters reveal the trend in HCAHPS scores prior to the onset of the pandemic. Each of these comparisons shown in Table V.H–1 includes the following:

a. Official HCAHPS top-box scoring that adjusts for survey mode and patient mix.

b. Restriction to hospitals with at least 25 completed surveys in each of the two matched quarters, so that the same types of hospitals that achieve 100 completes over four quarters for the Hospital VBP Program were used.

c. Comparison was restricted to the same hospitals one year earlier, so that differential participation of hospitals during the excepted reporting period (Q1 and Q2 2020) did not distort results.

d. Comparisons of parallel quarters were used, for example Q1 to Q1, to neutralize any seasonal effects.

Table V.H–1: Change in HCAHPS Top-Box scores in matched quarters, from Q1 2019 vs. Q1 2018, to Q3 2020 vs. Q3 2019.

Each column compares data from the named quarter to data from the same hospitals one year earlier, thus accounting for seasonal effects and patient-mix adjustment.

[956] *https://www.hcahpsonline.org/en/summary-analyses/.*

*Significant at p<0.05; **Significant p<0.005; ***Significant at p<0.0001. All bolded values are statistically significant

Notes: The Q3 2020 vs. Q3 2019 comparison is based upon ~98% of Q3 2020 hospitals that are expected to submit HCAHPS data.

Approximately 88% of hospitals in each pair of matched quarters are IPPS; approximately 12% are Critical Access Hospitals.

Standard HCAHPS scoring, including survey mode and patient-mix adjustment, has been applied.

					COVID-19 QUARTERS		
	Change in HCAHPS Top-Box Points						
HCAHPS Measure used in Hospital VBP	Q1 2019 vs. Q1 2018	Q2 2019 vs. Q2 2018	Q3 2019 vs. Q3 2018	Q4 2019 vs. Q4 2018	Q1 2020 vs. Q1 2019	Q2 2020 vs. Q2 2019	Q3 2020 vs. Q3 2019
Communication with Nurses	**0.55*** **	**0.13***	**0.17****	-0.01	-0.04	**-1.15*** **	**-1.40*** **
Communication with Doctors	**0.32*** **	**0.13***	**0.16****	0.07	0.00	**-0.91*** **	**-1.06*** **
Staff Responsiveness	**0.71*** **	0.05	0.11	**-0.18***	**-0.82***	**-2.06*** **	**-2.54*** **
Communication About Medicine	**0.50*** **	0.01	0.08	**-0.77*** **	**-1.23*** **	**-3.27*** **	**-3.05*** **
Cleanliness	**0.59*** **	0.10	**0.23****	0.12	**-0.63*** **	**-0.92*** **	**-2.44*** **
Quietness	0.05	**-0.36*** **	**0.26****	-0.16	**0.41****	**0.54*** **	**-0.20***
Discharge Information	0.02	**-0.15****	**0.12****	**0.17****	**0.20****	**-0.79*** **	**-0.69*** **
Care Transition	**0.78*** **	**0.53*** **	**0.54*** **	**0.34*** **	**0.25****	**-2.00*** **	**-1.96*** **
Overall Rating	**0.39*** **	-0.02	0.13	0.08	**0.77*** **	-0.19	**-1.41*** **
Number of hospitals in each pair of matched quarters	3326	3250	3198	3162	1606	1701	3074

Results show that for Q1 2019 to Q4 2019, scores generally increased compared to the same quarter one year earlier, with changes of <1 top-box point. During the first COVID–19 impacted quarter, Q1 2020, score differences were mixed, with top-box scores with sometimes >1 compared to a year earlier. That is, changes between Q1 2019 and Q1 2020 were both positive and negative, with some changes exceeding 1 top-box point.

During the COVID–19 impacted quarters of Q2 2020 and Q3 2020, scores were always lower than a year earlier, generally by 1–3 top-box points. These changes are statistically significant in all but one instance, often with p<0.0001, meaning that changes were too large to occur by chance more than one time in 10,000. These changes stand in sharp contrast to the patterns of small improvement prior to Q2 2020 discharges.

We note that, in accordance with the ECE granted in response to the COVID–19 PHE discussed more fully in section V.H.7 of the preamble of this proposed rule, submission of CY 2020 Q1 and Q2 HCAHPS data was optional. However, as previously mentioned, comparisons are based on hospitals with at least 25 completed surveys in each of the two matched quarters. We do not believe that such a significant change in hospital performance from the immediately preceding years for this measure would exist in the absence of the PHE for COVID–19.

Additionally, in the September 2020 IFC, we noted that we would not use any Q1 or Q2 CY 2020 data to calculate TPSs for the applicable fiscal years (85 FR 54835). Because the FY 2022 performance period for the HCAHPS measure is January 1, 2020 through December 31, 2020, we would only have six months of data (July 1, 2020 through December 31, 2020) to calculate hospital performance on this measure. We believe that the third and fourth CY 2020 data would continue to demonstrate a deviation in national performance such that scoring this measure would not be representative of national or individual hospital quality of care.

We also believe that suppressing this measure for the FY 2022 program year will address concerns about the potential unintended consequences of penalizing hospitals that treated COVID–19 diagnosed patients. Therefore, we believe it is appropriate to suppress the HCAHPS measure for the FY 2022 Hospital VBP program year.

We welcome public comment on our proposal to suppress the HCAHPS measure for the FY 2022 program year.

(3) Proposal To Suppress the Medicare Spending Per Beneficiary (MSPB) Measure (NQF #2158) for the FY 2022 Hospital VBP Program Year

Pursuant to the measure suppression policy discussion in section XX.H.1 of the preamble of this proposed rule, we are proposing to suppress the MSPB measure for the FY 2022 program year under proposed Measure Suppression Factor 4, significant national shortages or rapid or unprecedented changes in: (i) Healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix. Based on our analysis, we have found that hospitalizations involving COVID–19 overall tend to have higher mortality rates, longer lengths of stay, and higher observed, payment-standardized costs than hospitalizations without COVID–19. Based on our analysis, we believe that these rapid changes in patient case mix have significantly affected the MSPB measure. Under this proposal, we would calculate hospitals' MSPB measure rates, but we would not use these measure rates to generate achievement or improvement points for this measure. Additionally, because the MSPB measure is the only measure included in the Efficiency and Cost Reduction domain, we would not

calculate hospitals' FY 2022 Efficiency and Cost Reduction domain scores. Participating hospitals would continue to report the measure's data to CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report Q3 and Q4 2020 data where feasible and appropriately caveated.

We note that in the September 2020 IFC, we stated that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable fiscal years (85 FR 54835). We also note that the MSPB Hospital measure requires a 90-day lookback period to risk adjust the data appropriately. Third quarter CY 2020 data would require a lookback period of April 1, 2020 through July 1, 2020 for risk adjustments, but this period would fall within the excepted second quarter CY 2020 data. Therefore, for the FY 2022 program year, if we were to not suppress this measure, we would only be able to use hospital admissions data from Q4 of CY 2020 to calculate hospital scores for this measure.

We conducted an analysis to assess the impact of COVID–19 on hospitalizations and several specific components of the MSPB measure, including length of stay, cost of inpatient stay, and proxy MSPB hospital episode costs (all costs from 3 days prior to admission to 30 days post-discharge). This analysis used available data from January 1, 2020 through November 22, 2020. We focused on MS–DRGs as the unit of analysis and comparison to examine the impact of COVID–19 generally on hospitalizations. We applied several data processing steps to ensure data completeness: we restricted the study population to beneficiaries with continuous enrollment in Parts A and B and with Medicare as primary payer, and who had data from three days prior to the inpatient hospital admission through 30 days post-hospital discharge during the study period. The analysis also required inpatient claims with a valid discharge date and a positive standard allowed amount to ensure that only claims that were paid under Medicare Parts A and B were captured. These data processing steps ensured the appropriate beneficiary population and data validity.

During the study period, we observed significant impacts to patient case mix due to COVID–19. The majority of hospitals (67 percent) had at least one COVID–19 hospitalization, defined as the presence of a principal or secondary diagnosis for COVID–19 on the inpatient claim. There were nearly 250,000 COVID–19 hospitalizations, representing around 4 percent of all hospitalizations during the study period. As the study period ended in November 2020, our analysis does not capture increases in COVID–19 hospitalizations over the winter period. The MS–DRG with the highest share of COVID–19 hospitalizations was MS–DRG 177 for Respiratory Infections and Inflammations with Major Complication or Comorbidity (MCC), with over 70 percent of those admissions involving COVID–19. The effect of COVID–19 was not limited to respiratory care; in fact, we observed COVID–19 diagnoses across MS–DRGs in 25 Major Diagnostic Categories (MDCs) out of a total of 26 MDCs. The only MDC without any COVID–19 hospitalizations was MDC 15 for Newborns & Other Neonates with Conditions Originating in Perinatal Period. These results indicate that there were substantial changes to the patient case mix across the full range of care provided by hospitals due to the influx of patients with COVID–19.

Beyond the prevalence of COVID–19 amongst the hospital inpatient population, we tested the extent to which hospitalizations with COVID–19 appeared different from those without COVID–19. We found that the mean and median lengths of stays where patients were diagnosed with COVID–19 were longer compared to patients not diagnosed with COVID–19 (mean of 10 days compared to 7 days, respectively and median of 7 days compared to 5 days, respectively). We also examined various cost metrics, using payment-standardized amounts which remove the effect of the increased DRG payment weighting for hospitalizations with a COVID–19 diagnosis on the inpatient claim. The mean cost of hospitalizations with a COVID–19 diagnosis on the inpatient claim was 44 percent greater than the mean cost of hospitalizations without a COVID–19 diagnosis ($21,939 compared to $15,203). Our analysis was limited to examining inpatient hospitalizations, rather than the MSPB measure, as we focused on gaining a broader understanding of the changes to healthcare due to COVID–19. However, we did conduct some analyses to understand the post-discharge period as the MSPB measure includes a 30-day post discharge period. We compared the cost of a proxy episode by looking at the costs from 3 days prior to admission, the hospitalization, and 30 days after discharge for patients with and without a COVID–19 diagnosis on the inpatient claim. The mean cost for patients diagnosed with COVID–19 was 27 percent more than a hospital episode where the patient was not diagnosed with COVID–19 ($37,217 compared to $29,309). These results indicate that the differences in the cost of hospitalizations with and without COVID–19 extend to the post-discharge period. We believe that suppressing this measure for the FY 2022 program year would mitigate concerns about the impact of the significant changes in facility-level case mix and costs due to the PHE for COVID–19 on hospital performance and national comparability for this measure. Therefore, we believe it is appropriate to suppress the MSPB measure for the FY 2022 program year.

We welcome public comment on our proposal to suppress the MSPB measure for the FY 2022 program year.

(4) Proposal To Suppress the Five Healthcare-Associated Infection (HAI) Safety Measures for the FY 2022 Hospital VBP Program Year

In this proposed rule, we are proposing to suppress the five HAI Safety measures (CAUTI, CLABSI, Colon and Hysterectomy SSI, MRSA, and CDI) for the FY 2022 program year under proposed Measure Suppression Factor 1, significant deviation in national performance on the measures, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years. We are concerned that the COVID–19 PHE affected measure performance on the current HAI measures such that we will not be able to score hospitals fairly or reliably on them. We would calculate hospitals' five HAI measure rates, but we would not use these measure rates to generate achievement or improvement points for these measures. Additionally, because these five measures make up the entirety of the Safety domain, we would not calculate hospitals' FY 2022 Safety domain score. Participating hospitals would continue to report the measure's data to the CDC and CMS so that we can monitor the effect of the circumstances on quality measurement and determine the appropriate policies in the future. We would continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe. We also intend to publicly report CY 2020 Q3 and Q4 data where feasible and appropriately caveated.

The previously established FY 2022 performance period for the HAI

measures was January 1, 2020 through December 31, 2020. We note that in the September 2020 IFC, we stated that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable fiscal years because we were concerned with the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19 (85 FR 54835). However, we continue to be concerned about measure performance and the national comparability of such performance during the third and fourth quarter of CY 2020.

The CDC conducted an analysis which found that the CLASBI, CAUTI, and MRSA measures had statistically significant measure rate increases during the third and fourth quarter of CY 2020 as compared to the third and fourth quarter of CY 2019. We believe that this distortion in measure performance may be due to circumstances unique to the effects of the pandemic such as staffing shortages and turnover, patients that are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. In a March comparison run between Q4 2019 and Q4 2020 data for hospitals that submitted complete data for both quarters, there was a national percent change in the standardized infection ratio (SIR), or the primary summary measure used by the NHSN to track healthcare associated infections, of 48.1 percent for CLABSI, 18.8 percent for CAUTI and 33.8 percent for MRSA. For the SSI and CDI measures, neither measure had a statistically significant increase or decrease during the third and fourth quarter of CY 2020 as compared to the third and fourth quarter of CY 2019. For the SSI measure, the low reporting volume is due to the decrease in surgeries during the pandemic, while the CDI measure has historically been declining. Though the pandemic may not have the same clinical impact on the SSI and CDI measures, we believe that due to the low reporting volume of these two measures and for maintaining consistency of the full CDC NHSN HAI measure set, all five CDC NHSN HAI measures should be suppressed instead of just 3 of them. We are also concerned that if we were to suppress three measures in the Safety domain while continuing to score hospitals on the remaining two measures in the Safety domain, the Safety domain scores may be significantly better or significantly worse than in immediately preceding years. Therefore, we believe it is appropriate to suppress all five HAI measures in the Safety domain to ensure an accurate and reliable national comparison of performance on hospital safety.

In determining how to address the impact of the COVID–19 PHE on the five HAI measures, we also considered extending the FY 2022 performance periods for the five HAI measures so that they would include one full year of measure data. However, because the performance period for the FY 2022 program year began on January 1, 2020, we believe that changing the performance period after January 1, 2020 would be unfair and confusing for hospitals. Using data from CY 2019 would require us to score hospitals on data on which they have already been scored in the FY 2021 program year. Additionally, using data from CY 2021 would require us to change the performance periods for all future program years in order to avoid using the same data twice. Scoring hospitals on the same data for multiple program years may cause hospitals that have improved on their performance to be penalized more than once or allow hospitals that have not improved to be rewarded on their performance more than once. Further, changing the performance periods for these measures could incur administrative costs on hospitals that would be required to change their reporting systems and workflows.

We also considered making no modifications to the program and suppressing no measure data from CY 2020 for assessing FY 2022 HAI measure scores as an additional alternative to using the measure suppression policy. This alternative would be operationally easier to implement but would mean assessing participating hospitals using quality measure data that has been impacted by the COVID–19 PHE without additional adjustments to the measures. Additionally, given the geographic disparities in the COVID–19 PHE's effects, this policy could place hospitals in regions that were hit harder by the pandemic at a disadvantage. Ultimately, we believe that our proposal to suppress the HAI measure data from CY 2020 more fairly addresses the impact of the COVID–19 PHE on participating hospitals. Therefore, in order to maintain program consistency and avoid scoring hospitals on the same data for more than one program year, we are proposing to suppress all five HAI measures in the Safety domain for the entire FY 2022 program year.

We welcome public comment on our proposal to suppress the five HAI measures for the FY 2022 program year.

(5) Proposal To Suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) Measure (NQF #0468) for the FY 2023 Program Year

In this proposed rule, we are proposing to suppress the MORT–30–PN measure beginning with the FY 2023 program year under proposed Measure Suppression Factor 2, clinical proximity of the measure's focus to the relevant disease pathogen or health impacts of the national PHE. COVID–19 is caused by SAR–CoV–2, which begins when respiratory droplets containing the virus enter an individual's upper respiratory tract. Pneumonia has been identified as a typical characteristic of individuals infected with COVID–19,[957] and our analysis based on data from CY 2020 shows that a substantial portion of the MORT–30–PN measure cohort includes admissions with either a principal or a secondary diagnoses of COVID–19. In addition, almost all of the admissions with a COVID–19 diagnosis have a principal diagnosis of sepsis; observed mortality rates for these admissions are extremely high and are substantially higher than admissions without a COVID–19 diagnosis. Finally, observed mortality rates in admissions without a COVID–19 diagnosis (using data from April 2020 through June 2020) are higher than observed mortality rates from the prior year. For the currently available data for this measure, there is a high percentage of Medicare beneficiaries with a secondary diagnosis of COVID–19 in the measure cohort during CY 2020. We would calculate hospitals' MORT–30–PN measure rates, but we would not use these measure rates to generate achievement and improvement points for this measure. We will continue to monitor the claims that form the basis for this measure's calculations to evaluate the effect of the circumstances on quality measurement and to determine the appropriate policies in the future. We would also continue to provide confidential feedback reports to hospitals as part of program activities to ensure that they are made aware of the changes in performance rates that we observe.

As previously discussed, the FY 2022 MORT–30–PN performance period is September 1, 2017 through June 30, 2020. However, in the September 2020 IFC, we noted that we would not use any first or second quarter CY 2020 data to calculate TPSs for the applicable fiscal years (85 FR 54835). With this

exception, the FY 2022 performance period for this measure would only be affected by a shortened performance period (September 1, 2017 through December 31, 2019) that does not use data from the COVID–19 PHE. Therefore, we have decided that it is not necessary to suppress this measure for the FY 2022 program year. However, given the ongoing status of the PHE and the impact of COVID–19 on this measure data, we are proposing to suppress this measure for the FY 2023 program year.

Our analysis of the MORT–30–PN measure data showed that the MORT–30–PN cohort had a higher proportion of patients with a secondary diagnosis of COVID–19 than the cohorts for the other condition-specific mortality measures used in the Hospital VBP Program, and that these patients have a higher risk of mortality than the remainder of the patients included in the pneumonia measure cohort.

Table V.H-2: Percent of COVID-19 Diagnoses in Mortality Measure Cohorts, March – September 2020

Mortality Measure Cohort	March 2020	April 2020	May 2020	June 2020	July 2020	August 2020	September 2020
Pneumonia	6.7	20.9	15.4	8.6	13.9	13.3	9.4
COPD	0.3	0.4	0.2	0.3	0.4	0.6	0.5
AMI	0.1	0.6	0.7	0.5	0.9	1.1	0.8
HF	0.2	0.5	0.7	0.6	0.7	0.8	0.6
THA/TKA	0.0	0.4	0.2	0.1	0.1	0.2	0.1
CABG	0.0	0.3	0.2	0.2	0.3	0.3	0.3
Stroke	0.0	1.1	1.2	0.8	1.2	1.2	1.3

Table V.H-3: Observed Mortality Rate for Admissions with Secondary Diagnosis of COVID-19 POA for the MORT-30-PN Measure, April 2020 – June 2020

	Number of Admissions	Number of Deaths	Observed 30-Day Mortality Rate
Admissions with Secondary Diagnosis of COVID-19 POA	10,285	5,059	49.2%
Admissions without a Diagnosis of COVID-19	61,418	11,845	19.3%

Data from September 2020 also showed that although admission volumes for the MORT–30–PN cohort were substantially lower compared to admission volumes for this cohort in September 2019, the observed mortality rates for this cohort were statistically significantly higher in September 2020 when compared to the observed mortality rates for this cohort during the same period in 2019.

Our analyses also demonstrated that almost all of the COVID–19 patients captured in the MORT–30–PN measure

cohort likely represent a distinct, severely ill group of patients (with a mortality rate of 49.2 percent as compared 23.8 percent for patients without a COVID–19 diagnosis) for whom it may be difficult to adequately ascertain appropriate risk adjustment. In addition, our analyses found that the odds ratio of mortality for COVID–19 as a risk factor was very high (4.67, 95 percent confidence interval: 4.45–4.90) as compared to other diagnoses such as metastatic cancers, acute leukemia, and other severe cancers (2.16, 95 percent confidence interval: 2.05–2.28), protein-calorie malnutrition (1.64, 95 percent confidence interval: 1.57–1.71), dementia or specified brain disorders (1.58, 95 percent confidence interval: 1.51–1.64), and chronic liver disease (1.50, 95 percent confidence interval: 1.37–1.64). We also calculated the Pearson correlation between the change in observed 30-day pneumonia mortality rate and Medicare COVID–19 burden (defined as COVID–19-related hospitalizations per Medicare beneficiary) for both a 3-months (March-May) and 12-months (June-May) period. That is, we calculated the change in observed 30-day pneumonia mortality rates between March-May 2019 (3-months) and March-May 2020, and also between June 2018-May 2019 and June 2019-May 2020 (12-months). We then assessed the correlation between these changes in observed pneumonia mortality rates and Medicare COVID–19 burden. Changes in observed 30-day pneumonia mortality rates were highly and statistically significantly correlated with Medicare COVID–19 burden when analyzing the 3-month and 12-month periods (Pearson correlation of 0.77 and 0.69, respectively).

We considered whether we could exclude patients with a diagnosis of COVID–19 from the MORT–30–PN cohort, but we determined suppression will provide us with additional time and additional months of data potentially impacted by COVID–19 to more thoroughly evaluate a broader range of alternatives, given the month-to-month variation in the percent of COVID–19 diagnoses as shown in Table V.H–3. We want to ensure that the measure reflects care provided by the hospital to Medicare beneficiaries admitted with pneumonia and we are concerned that excluding a significant proportion of all eligible patients may not accurately reflect the care provided, particularly given the unequal distribution of COVID–19 patients across hospitals over time. We believe that suppressing this measure beginning with the FY 2023 program year would address this concern.

As part of our analysis, we also evaluated the impact of suppressing the MORT–30–PN measure on hospital eligibility, program scoring, and payment for FY 2023. We used data from the most recently completed program year, FY 2021, to simulate removal of the MORT–30–PN measure as compared to the baseline data.[958] For purposes of this simulation, we assumed that all other measures in the Hospital VBP Program would remain in the program and that hospital performance on these measures would remain unchanged from their historical performance on these measures. Based on this simulation, we found that the suppression of the MORT–30–PN measure resulted in less than a one percent decrease in overall eligibility for the Hospital VBP Program; the average TPS for participating hospitals decreased by 0.4 points; and the number of hospitals receiving a payment increase was reduced by one percentage point. Therefore, we believe that suppressing the MORT–30–PN measure minimizes negative impacts on the eligibility, scoring and payment distributions under the Hospital VBP Program and at this time we are not proposing to make any changes to the FY 2023 scoring methodology as a result.

We invite public comment on our proposal to suppress the MORT–30–PN measure for the FY 2023 program year.

2. FY 2022 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details. We note that in section V.H.1. of the preamble of this proposed rule, we are proposing to suppress several measures in the Hospital VBP Program for the FY 2022 Program Year. If these policies are finalized each hospital would receive the payment reduction for the Hospital VBP Program as required by statute, but every hospital would receive a value-based incentive payment amount that matches the payment reduction amount. However, if the policies in section V.H.1. of the preamble of this proposed rule are not finalized, the FY 2022 program year payment details would be as described in this section. Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2022 program year is two percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2022 is approximately $1.9 billion, based on the December 2020 update of the FY 2020 MedPAR file. We intend to update this estimate for the FY 2022 IPPS/LTCH PPS final rule using the March 2021 update of the FY 2020 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we would utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We would then calculate a value-based incentive payment adjustment factor to apply to the base operating DRG payment amount for each discharge occurring in FY 2022, on a per-claim basis. Applying the current scoring methodology without any modifications reflecting the proposals in this proposed rule, we are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). The TPSs from the FY 2021 program year are the basis for the proxy factors. These FY 2021 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. We note that the FY 2021 TPSs were calculated using measure data from before the PHE due to COVID–19 was declared. Actual TPSs for the FY 2022 program year may be more variable than the FY 2021 TPSs due to the impacts of the COVID–19 PHE on FY 2022 data. We refer readers to sections V.H.1. and V.H.6. of the preamble of this proposed rule for additional information on the impacts of the COVID–19 PHE on the Hospital VBP Program. The slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in Table 16 is 2.6527024687. This slope, along with the estimated amount

[958] We note that this analysis did not include the MORT–30–CABG measure because it is not included in the Hospital VBP Program until FY 2022 (81 FR 56996 through 56998).

available for value-based incentive payments, is also published in Table 16.

If our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we will not update Table 16 as Table 16A in the final rule. However, if those proposals are not finalized, we would update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2021 update to the FY 2020 MedPAR file. We would also update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2022 would continue to be based on historic FY 2021 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2022 program year before the FY 2022 IPPS/LTCH PPS final rule is published.

If our proposals to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount are finalized, we will also not post Table 16B (which we typically do to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the applicable program year, after hospitals have been given an opportunity to review and correct their actual TPSs).

3. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program, the statute does not require that the measure continue to remain in the Hospital IQR Program.

We are not proposing any changes to these policies in this proposed rule.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), we finalized measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. We are not proposing any changes to these policies in this proposed rule.

c. Proposed Removal of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (NQF #0531) Beginning With the FY 2023 Program Year

We are proposing to remove the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure (NQF #0531) from the Hospital VBP Program under removal Factor 8—the costs associated with the measure outweigh the benefit of its use in the program. Factor 8 is a measure removal factor finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446).

We adopted the CMS PSI 90 composite measure (NQF #0531) in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38251 through 38256) beginning with the FY 2023 program year to encourage improvement in patient safety for all hospitals, and we also adopted a performance period for that program year that runs from July 1, 2019 through June 30, 2021. We continue to consider patient safety a high priority, but because the CMS PSI 90 measure is also used in the HAC Reduction Program, we believe removing this measure from the Hospital VBP Program will reduce the provider and clinician costs associated with tracking duplicative measures across programs. We noted in prior rulemaking that we would continue to monitor the HAC Reduction Program and Hospital VBP Program and analyze the impact of our measure selection, including any unintended consequences with having a measure in more than one program, and would revise the measure set in one or both programs if needed (82 FR 38255). Since then, we have considered the impact of having the CMS PSI 90 measure in both the HAC Reduction Program and the Hospital VBP Program. We note that the modified version of the CMS PSI 90 measure was adopted for use in the FY 2018 HAC Reduction Program as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57020). While both programs will require reporting on the same measure beginning in FY 2023, we have reconsidered whether the differences in the scoring methodologies for measuring performance in these two programs presents unneeded complexity in tracking duplicative measures while accounting for differences in applicability.

For example, the scoring methodology for the CMS PSI 90 measure for the Hospital VBP Program includes comparing an individual hospital's performance during the performance period to all hospitals' performance during an established baseline period and a hospital can be awarded improvement points by comparing an individual hospital's performance during the performance period to that same individual hospital's performance from the baseline period; the HAC Reduction Program assesses performance using an equally weighted average of scores across measures included in the program and does not require a baseline period for scoring purposes. Hospitals may also incur additional cost to monitor measure performance and potential payment impact in two programs, given that each program has a different scoring methodology that applies to the same measure. We also believe removing the CMS PSI 90 measure from the Hospital VBP Program is appropriately responsive to feedback from stakeholders who have noted that using the same measure in different programs creates additional administrative costs to hospitals rather than further incentivizing improved performance. We have noted in previous years that we believe costs are multifaceted and include not only the burden associated with reporting, but also the costs CMS incurs to implement and maintain the measure in the program (83 FR 41442). Maintaining this measure in both the HAC Reduction Program and the Hospital VBP Program and applying two different scoring methodologies requires CMS to expend resources for analyzing performance and developing duplicative feedback reports for its use in both programs. For example, due to the differences in scoring methodologies between the HAC Reduction Program and the Hospital VBP Program, CMS maybe required to utilize and maintain multiple versions of the CMS PSI software used to calculate PSIs and the composite measure across the two programs. Further, since 2017, we have worked to reduce regulatory burden on hospitals, lower health care costs, and enhance patient care by streamlining the quality reporting and value-based purchasing programs through the Meaningful Measures Framework. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a broader discussion of the Meaningful Measures Framework (83 FR 41147). Two of the primary

objectives of the Meaningful Measures Framework are to include quality measures for which there is significant opportunity for improvement and to minimize the level of burden for providers. We recognize that the Hospital VBP Program currently uses five other patient safety-focused measures (CAUTI, CLABSI, CDI, MRSA, and SSI) that are also used under the HAC Reduction Program. As noted in prior rulemaking, we continue to monitor and analyze measures that are in both the HAC Reduction Program and Hospital VBP Program to assess the impact of having a measure in more than one program and to revise the measure set in one or both programs if needed (82 FR 38255). We focused our initial analysis on the impact of the CMS PSI 90 measure in the Hospital VBP Program rather than the other five patient safety-focused measures because we believe it would be least burdensome to remove now, before hospitals are required to begin reporting on the measure for the FY 2023 Hospital VBP program year. Furthermore, as previously noted, the Hospital VBP Program requires that the software used to calculate measure scores between the baseline and performance period must match, whereas the HAC Reduction Program does not include baseline periods and can therefore more easily implement measure scoring. At this time, we believe there is significant opportunity for the remaining five patient safety-focused measures to continue encouraging improvement in patient safety in both the Hospital VBP Program and the HAC Reduction Program and will continue to monitor and analyze the impact of these measures and assess the need for revisions in future rulemaking. We note that the Hospital VBP Program uses the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and relies on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program.

Accordingly, for the previously discussed reasons, we are proposing to remove the CMS PSI 90 measure from the Hospital VBP Program beginning with the FY 2023 program year.

We welcome public comment on this proposal to remove the CMS PSI 90 measure beginning with FY 2023.

d. Updates to the Specifications of Four Condition-Specific Mortality Measures and One Procedure-Specific Complication Measure Beginning With the FY 2023 Program Year To Exclude Patients Diagnosed With COVID–19

We are updating the following four condition-specific mortality measures and one procedure-specific complication measure to exclude patients with either principal or secondary diagnoses of COVID–19 from the measure denominators beginning with the FY 2023 program year.

- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0230)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2558)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1893)
- Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure Hospitalization (NQF #0229)
- Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1550).

We note that we do not need to update these measures for the FY 2022 program year because the only data that would have been affected by the PHE for COVID–19 is from the first and second quarters of CY 2020, which are excluded under the ECE we granted in response to the PHE for COVID–19.

The measures we have adopted for the Hospital VBP Program are not currently specified to account for how the presence of a COVID–19 might impact the quality of care assessed by those measures. To determine this impact, we analyzed the relationship between COVID–19 and the measure cohorts for each of the applicable conditions/procedures for the Hospital VBP Program measures, as previously listed. For these measures, we calculated the Pearson correlation between changes in observed 30-day mortality rates and Medicare COVID–19 burden (defined as COVID–19-related hospitalizations per Medicare beneficiary) for both a 3-month (March-May) and 12-month (June-May) period. That is, we calculated the change in observed 30-day mortality rates between March-May 2019 (3-months) and March-May 2020, and also between June 2018-May 2019 and June 2019-May 2020 (12-months). We then assessed the correlation between these changes in observed mortality rates and Medicare COVID–19 burden. Changes in observed 30-day mortality rates showed no or modest but statistically significant correlation with Medicare COVID–19 burden when analyzing a 3-month period for the non-pneumonia measures in the Hospital VBP Program; however, there was no significant correlation for the non-pneumonia measures when analyzing the 12-month period. Because the performance periods for these measures are each three years and there is no significant correlation between the change in mortality with Medicare COVID–19 burden over a 12-month period (using COVID-impacted data through May 2020), we believe these measure scores will be valid and equitable for use in the Hospital VBP Program.

In the FY 2015 IPPS/LTCH PPS final rule, we finalized a technical updates policy which included a subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital VBP Program (79 FR 50077 through 50079). We stated that these non-substantive updates might include exclusions to a measure (citing as an example the addition of a hospice exclusion to the 30-day mortality measures) (79 FR 50078). Due to the impact of the COVID–19 PHE on the mortality and complications measures used in the Hospital VBP Program, as described previously, we are updating the MORT–30–AMI, MORT–30–CABG, MORT–30 COPD, MORT–30–HF, and COMP–HIP–KNEE measures to exclude admissions with either a principal or secondary diagnosis of COVID–19 from the measure denominators. This technical update will modify these four condition-specific mortality measures and one procedure-specific complication measure to exclude certain ICD–10 Codes that identify patients with a principal or secondary diagnosis of COVID–19 from the measure denominators but will retain the measures in the program.

We believe that excluding COVID–19 patients from the measure denominator beginning with the FY 2023 program year and subsequent years will ensure that these four condition-specific mortality measures and one procedure-specific complication measure continue to account for mortality and complication rates as intended and meet the goals of the Hospital VBP Program. Technical specifications of the Hospital VBP Program measures are provided on our website under the Measure Methodology Reports section (available at: *http://www.cms.gov/Medicare/*

Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html). Additional resources about the measure technical specifications and methodology for the Hospital VBP Program are on the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/hvbp*).

e. Summary of Previously Adopted Measures for FY 2022 Through FY 2025 Program Years

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58849 through 58850) for summaries of previously adopted measures for the FY 2023 and FY 2024 program years, and to the tables in this section showing summaries of previously adopted measures for the FY 2023, FY 2024, and FY 2025 program years. We are proposing to remove the CMS PSI 90 measure from the Hospital VBP Program beginning with the FY 2023 program year. We are also proposing to suppress the HCAHPS, MSPB, and HAI measures for the FY 2022 program year, and to suppress the MORT–30–PN measure for FY 2023. We are not proposing to add new measures at this time. If these measure proposals are finalized as proposed, the Hospital VBP Program measure set for the FY 2022, FY 2023, FY 2024 and FY 2025 program years would, as of now, contain the following measures:

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Table V.H-4: Summary of Measures for the FY 2022 Program Year if Measure Proposals are Finalized		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS*	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI*	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI*	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI*	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI*	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB*	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* Per section V.H.1.b. of the preamble of this proposed rule, we are proposing to suppress the HCAHPS, MSPB, and HAI measures for the FY 2022 program year.

Table V.H-5: Summary of Measures for the FY 2023, FY 2024, and FY 2025 Program Years if Measure Proposals are Finalized		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN* (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG*	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* Per section V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to suppress the MORT-30-PN measure for FY 2023 and exclude patients with a principal or secondary diagnosis of COVID-19 from the measure denominators in the remaining condition-specific mortality measures.

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4. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for a previously finalized schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42393 through 42395), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58850 through 58854) for additional previously adopted baseline and performance periods for the FY 2023 and subsequent program years. As discussed in sections V.H.3.c and V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to remove the CMS PSI 90 measure and suppress the MORT–30–PN measure for the FY 2023 program year.

b. Proposal To Update the Baseline Periods for Certain Measures due to the Extraordinary Circumstances Exception Granted in Response to the COVID–19 PHE

(1) Background

We previously finalized baseline and performance periods for the FY 2023, 2024, 2025, 2026, and 2027 program years for all the measures included in the Hospital VBP Program, and we refer the reader to Table V.H–5 for those previously adopted baseline and performance periods. However, subsequent to finalizing those baseline periods, and as described further in section V.H.7., we granted an ECE in response to the COVID–19 PHE and stated that we will not use any first or second quarter of CY 2020 measure data that was voluntarily submitted for scoring purposes under the Hospital VBP Program.

If we simply removed the first and second quarter of CY 2020 measure data from the previously finalized baseline periods for the FY 2024 program year the baseline period for certain measures included in the Hospital VBP Program would only be six months, which is too short for purposes of calculating reliable baseline period scores.

Accordingly, to ensure that we have a sufficient quantity of data for baselining purposes, we are proposing several updates to the baseline periods in this proposed rule for the FY 2024 program year. We believe that the previously established baseline periods for FY 2022, FY 2025, and FY 2026 program years are not impacted. There are also measures whose quantity of data for baselining purposes would be impacted by the ECE for the FY 2027 program year. However, for these measures, we believe 30 and 33-month baseline periods still provide enough data to reliably calculate baseline scores.

(2) Proposal To Update the FY 2024 Baseline Period for the Person and Community Engagement Domain Measure (HCAHPS Survey)

For the Person and Community Engagement Domain Measure (HCAHPS Survey), we finalized that the baseline period for the FY 2024 program year would be January 1, 2020 through December 31, 2020, but the removal of the January-June data would only leave us with six months of data. We believe that using at least a full year for data collection provides high levels of data accuracy and reliability for scoring hospitals on this measure (76 FR 2458). Therefore, we are proposing to use a baseline period of January 1, 2019 through December 31, 2019 so that we have a full year of data. This baseline period would be paired with the previously finalized performance period of January 1, 2022 through December 31, 2022. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2024 scoring. We selected this revised data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal effects.

We note that this new proposed baseline period would not include the third or fourth quarters of 2020, even though those quarters were not included in the ECE. However, our internal analyses indicates that the average number of completed surveys, and thus average reliability of the measure as a whole, is higher when based on four consecutive quarters as opposed to two quarters of HCAHPS data. In addition, because hospitals must report at least 100 completed surveys for a performance period to receive an HCAHPS measure score, reducing the baseline period from 12 to six months would result in fewer hospitals, especially smaller hospitals, being able to report 100 surveys for the performance period. We estimate that 11 percent of the hospitals that would be able to achieve 100 completed surveys over four quarters would be unable to do so in two quarters. As a result, we believe using four consecutive quarters of data for the baseline period will provide a higher level of data accuracy and reliability for scoring hospitals on the HCAHPS Survey.

(3) Proposal To Update the FY 2024 Baseline Period for the Safety Domain Measures

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized the performance period for all measures in the Safety domain to run on the calendar year two years prior to the applicable program year and a baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent program years. For FY 2024, the baseline period for the Safety Domain Measures would be January 1, 2020 through December 31, 2020, but the removal of data impacted by the ECE from January to June of 2020 would only leave us with six months of data. We believe that using at least a full year for data collection provides high levels of data accuracy and reliability for scoring hospitals on measures (76 FR 2458). Therefore, we are proposing to update the FY 2024 baseline period for the Safety domain measures from January 1, 2020 through December 31, 2020 to January 1, 2019 through December 31, 2019 so that we have a full year of data. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2024 scoring. We selected this data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal affects.

(4) Proposal To Update the FY 2024 Baseline Period for the Efficiency and Cost Reduction Domain Measure

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized a 12-month performance period for the MSPB measure that runs on the calendar year two years prior to the applicable program year and a 12-month baseline period that runs on the calendar year four years prior to the applicable program year for the FY 2019 program year and subsequent years. For FY 2024, the baseline period for the MSPB measure would be January 1, 2020 through December 31, 2020, but the removal of data impacted by the ECE from January to June of 2020 would only

leave us with six months of data. We believe that using at least a full year for data collection provides high levels of data accuracy and reliability for scoring hospitals on measures (76 FR 2458). Therefore, we are proposing to update the FY 2024 baseline period for the MSPB measure from January 1, 2020 through December 31, 2020 to January 1, 2019 through December 31, 2019 so that we have a full year of data. We believe using data from this period will provide sufficiently reliable data for evaluating hospital performance that can be used for FY 2024 scoring. We selected this data period because it would provide the most consistency for hospitals in terms of the comparable length to previous program years and the performance period, and it would capture a full year of data, including any seasonal affects.

We welcome public comment on our proposals to update the FY 2024 baseline periods for the measures included in the Person and Community Engagement, Safety, and Efficiency and Cost Reduction domains.

c. Summary of Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2023 Through FY 2027 Program Years

The following tables summarize the baseline and performance periods that we have previously adopted and those that we are proposing to adopt.

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Table V.H-6: Previously Adopted Baseline and Performance Periods for the FY 2023 Program Year

Domain	Baseline Period	Performance Period
Person and Community Engagement • HCAHPS	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021
Clinical Outcomes • Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** • COMP-HIP-KNEE	• July 1, 2013 – June 30, 2016 • April 1, 2013 – March 31, 2016	• July 1, 2018 – June 30, 2021* • April 1, 2018 – March 31, 2021*
Safety✦ • NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021
Efficiency and Cost Reduction • MSPB	• January 1, 2019 – December 31, 2019	• January 1, 2021 – December 31, 2021

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting; CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then updated in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see section V.H.7. of the preamble of this proposed rule.

** Per section V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section XX.X.3.c. of the preamble of this proposed rule, we are proposing to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-7: Previously Adopted and Newly Proposed Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2019 – December 31, 2019*	● January 1, 2022 – December 31, 2022
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2014 – June 30, 2017 ● April 1, 2014 – March 31, 2017	● July 1, 2019 – June 30, 2022* ● April 1, 2019 – March 31, 2022*
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2019 – December 31, 2019*	● January 1, 2022 – December 31, 2022
Efficiency and Cost Reduction ● MSPB	● January 1, 2019 – December 31, 2019*	● January 1, 2022 – December 31, 2022

*These performance and baseline periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting; CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then updated in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see section V.H.7. of the preamble of this proposed rule. As discussed in section V.H.4.b. of the preamble of this proposed rule, we are proposing to update the baseline periods for the measures included in the Person and Family Engagement, Safety, and Efficiency and Cost Reduction domains.

** Per section V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of the preamble of this proposed rule, we are proposing to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-8: Previously Adopted Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2015 – June 30, 2018 ● April 1, 2015 – March 31, 2018	● July 1, 2020 – June 30, 2023 ● April 1, 2020 – March 31, 2023*
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023
Efficiency and Cost Reduction ● MSPB	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting; CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then amended in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see section V.H.7. of the preamble of this proposed rule.

** Per section V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of the preamble of this proposed rule, we are proposing to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-9: Previously Adopted Baseline and Performance Periods for the FY 2026 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)* ● COMP-HIP-KNEE	● July 1, 2016 – June 30, 2019 ● April 1, 2016 – March 31, 2019	● July 1, 2021 – June 30, 2024 ● April 1, 2021 – March 31, 2024
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024
Efficiency and Cost Reduction ● MSPB	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024

* Per section V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of the preamble of this proposed rule, we are proposing to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

Table V.H-10: Previously Adopted Baseline and Performance Periods for the FY 2027 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2023 – December 31, 2023	● January 1, 2025 – December 31, 2025
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort)** ● COMP-HIP-KNEE	● July 1, 2017 – June 30, 2020* ● April 1, 2017 – March 31, 2020*	● July 1, 2022 – June 30, 2025 ● April 1, 2022 – March 31, 2025
Safety✦ ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	● January 1, 2023 – December 31, 2023	● January 1, 2025 – December 31, 2025
Efficiency and Cost Reduction ● MSPB	● January 1, 2023 – December 31, 2023	● January 1, 2025 – December 31, 2025

*These performance periods are impacted by the ECE granted by CMS on March 22, 2020, the scope of which was further explained in a CMS memorandum issued on March 27, 2020 (see *CMS press release available at https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting; CMS memorandum available at https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*), and then amended in the August 25th COVID-19 IFC (*85 FR 54820*). For more detailed information, see section V.H.7. of the preamble of this proposed rule.

** Per section V.H.1.b.(5). of the preamble of this proposed rule, we are proposing to suppress the MORT-30-PN measure for the FY 2023 program year.

✦ As discussed in section V.H.3.c. of the preamble of this proposed rule, we are proposing to remove the CMS PSI-90 measure beginning with the FY 2023 program year.

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5. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to sections 1886(o)(3)(A) through 1886(o)(3)(D) of the Act for the performance standard requirements under the Hospital VBP Program. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program. We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58856 through 58857) for previously established performance standards for the FY 2023 program year. We note that the measure suppression proposals for the FY 2022 and FY 2023 program years, discussed more fully in section V.H.1. of the preamble of this proposed rule, will not affect the performance standards for the FY 2022 or FY 2023 program year. However, as discussed in section X.H.6. of the preamble of this proposed rule, we are proposing to not generate achievement or improvement points for any suppressed measures for FY 2022.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for further discussion on performance standards for which the measures are calculated with lower values representing better performance (85 FR 58855).

b. Previously Established and Estimated Performance Standards for the FY 2024 Program Year

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472), we established performance standards for the FY 2023 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41471 through 41472), we established, for the FY 2023 program year, the performance standards for the Safety domain measure, CMS PSI 90. However, as discussed in section V.H.3.c. of the

preamble of this proposed rule, we are proposing to remove the CMS PSI 90 measure from the Hospital VBP Program beginning with the FY 2023 program year. For this reason, we are not providing the estimated performance standards for this measure in this proposed rule. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. As discussed in section V.H.4.b. of the preamble of this proposed rule, we are proposing to update the FY 2024 program year baseline periods for the measures included in the Safety, Person and Community Engagement, and Efficiency and Cost Reduction domains. If finalized, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2024 program year for these measures.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are estimating additional performance standards for the FY 2024 program year. We note that the numerical values for the performance standards for the Safety and Person and Community Engagement domains for the FY 2024 program year in the following tables are estimates based on the most recently available data, and we intend to update the numerical values in the FY 2022 IPPS/LTCH PPS final rule.

The previously established and estimated performance standards for the measures in the FY 2024 program year are set out in the following tables.

Table V.H-11: Previously Established and Estimated Performance Standards for the FY 2024 Program Year

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain♦		
CAUTI*	0.650	0
CLABSI*	0.589	0
CDI*	0.520	0.01
MRSA Bacteremia*	0.726	0
Colon and Abdominal Hysterectomy SSI*	0.717 0.738	0 0
Clinical Outcomes Domain		
MORT-30-AMI#	0.866548	0.885499
MORT-30-HF#	0.881939	0.906798
MORT-30-PN (updated cohort)#	0.840138	0.871741
MORT-30-COPD#	0.919769	0.936349
MORT-30-CABG#	0.968747	0.979620
COMP-HIP-KNEE*#	0.027428	0.019779
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦ Per our proposal in section V.H.4.b. of the preamble of this proposed rule, the performance standards displayed in this table for the Safety domain measures were calculated using CY 2019 data.

* Lower values represent better performance.

Previously established performance standards.

The HCAHPS Base Score is calculated using the eight dimensions of the HCAHPS measure. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points. As discussed in section V.H.4.b. of the

preamble of this proposed rule, we are proposing to update the FY 2024 program year baseline period for the measure included in the Person and Community Engagement domain. If finalized, according to our established methodology for calculating performance standards, we will use data from January 1, 2019 through December 31, 2019 to calculate performance standards for the FY 2024 program year for this measure.

Table V.H-12: Estimated Performance Standards for the FY 2024 Program Year: Person and Community Engagement Domain±

HCAHPS Survey Dimension	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	53.50	79.42	87.71
Communication with Doctors	62.41	79.83	87.97
Responsiveness of Hospital Staff	40.40	65.52	81.22
Communication about Medicines	39.82	63.11	74.05
Hospital Cleanliness & Quietness	45.94	65.63	79.64
Discharge Information	66.92	87.23	92.21
Care Transition	25.64	51.84	63.57
Overall Rating of Hospital	36.31	71.66	85.39

± Per our proposal in section V.H.4.b. of the preamble of this proposed rule, the performance standards displayed in this table for the Persona and Community Engagement domain measures were calculated using CY 2019 data.

c. Previously Established Performance Standards for Certain Measures for the FY 2025 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2025 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58858), we established, for the FY 2025 program year, the performance standards for the Safety domain measure, CMS PSI 90. However, as discussed in section V.H.3.c. of the preamble of this proposed rule, we are proposing to remove the CMS PSI 90 measure from the Hospital VBP Program starting with the FY 2023 program year. For this reason, we are not including performance standards for this measure in this proposed rule. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established and newly established performance standards for these measures are set out in the following table.

Table V.H-13: Previously Established Performance Standards for the FY 2025 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
Clinical Outcomes Domain		
MORT-30-AMI	0.869247	0.887868
MORT-30-HF	0.882308	0.907733
MORT-30-PN (updated cohort)	0.840281	0.872976
MORT-30-COPD	0.916491	0.934002
MORT-30-CABG	0.969499	0.980319
COMP-HIP-KNEE*	0.025396	0.018159
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

d. Previously Established Performance Standards for Certain Measures for the FY 2026 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58858 through 588589), we established performance standards for the FY 2026 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

The previously established performance standards for these measures are set out in the following table.

Table V.H-14: Previously Established Performance Standards for the FY 2026 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
Clinical Outcomes Domain		
MORT-30-AMI	0.872624	0.889994
MORT-30-HF	0.883990	0.910344
MORT-30-PN (updated cohort)	0.841475	0.874425
MORT-30-COPD	0.915127	0.932236
MORT-30-CABG	0.970100	0.979775
COMP-HIP-KNEE*	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

e. Newly Established Performance Standards for Certain Measures for the FY 2027 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2027 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in the following table.

Table V.H-15: Newly Established Performance Standards for the FY 2027 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Clinical Outcomes Domain**		
MORT-30-AMI	0.877824	0.893133
MORT-30-HF	0.887571	0.913388
MORT-30-PN (updated cohort)	0.844826	0.877204
MORT-30-COPD	0.917395	0.932640
MORT-30-CABG	0.971149	0.980752
COMP-HIP-KNEE*	0.023322	0.017018
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** As discussed further in section V.H.7. of the preamble of this proposed rule, we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards.

6. Proposed Scoring Methodology and Data Requirements

a. Proposed Scoring Methodology for the FY 2022 Program Year Due to the PHE for COVID–19

As described in section V.H.1. of the preamble of this proposed rule, we are proposing to suppress seven measures in the Hospital VBP Program for FY 2022 and to use a special rule for FY 2022 scoring. As previously discussed, we are proposing that we would calculate measure rates for all measures in the FY 2022 program year. For measures that we propose to suppress, we would not use the measure rates to generate achievement and improvement points within the Hospitals VBP's current scoring methodology. We further propose under this special rule that we would only calculate achievement and improvement points, as well as a domain score, for the Clinical Outcomes Domain and that, because no other domains receive scores for the FY 2022 Program year, we would not award TPSs to any hospital for FY 2022.

Because no hospital would receive a TPS for FY 2022, we further propose that we would reduce each hospital's base-operating DRG payment amount by 2 percent, as required under section 1886(o)(7)(B) of the Act, and then assign to each hospital a value-based incentive payment amount that matches the 2 percent reduction to the base operating DRG payment amount. The net result of these payment adjustments would be neutral for hospitals. We have stated that value-based payment systems should rely on a mix of standards, processes, outcomes, and patient experience measures (76 FR 26491). As such, the Hospital VBP Program scoring methodology was developed to be used with several measures across multiple domains and aims to score hospitals on their overall achievement relative to national benchmarks. However, as discussed in the measure suppression proposals in section V.H.1., the data from several measures is significantly impacted by the COVID–19 PHE. Awarding negative or positive incentive payment adjustment percentages using TPSs calculated using the current scoring methodology would not provide a representative score of a hospital's overall performance in providing quality of care during a pandemic.

In order to ensure that hospitals are aware of changes in their performance rates that we have observed, we are proposing to provide FY 2022 confidential feedback reports that contain the measure rates we have calculated for the FY 2022 program year, along with achievement and improvement scores for the measures in the Clinical Outcomes Domain and a Clinical Outcomes Domain score. However, as previously discussed, we are proposing that the measure rates and Clinical Outcome Domain performance scores would not be used to calculate TPSs for the purpose of adjusting hospital payments under the FY 2022 Hospital VBP Program.

We invite public comment on these proposals.

b. Domain Weighting for the FY 2023 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. We are not proposing any changes to these domain weights in this proposed rule.

c. Domain Weighting for the FY 2023 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085) we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, for the FY 2017 program year and subsequent years. Hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted (79 FR 50084 through 50085). We are not

proposing any changes to these domain weights in this proposed rule.

d. Minimum Numbers of Measures for Hospital VBP Program Domains

We refer readers to the 2018 IPPS/LTCH PPS final rule (82 FR 38266) for our previously finalized requirements for the minimum numbers of measures for hospitals to receive domain scores. We are not proposing any changes to these policies in this proposed rule.

e. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41465 through 41466); the FY 2020 IPPS/LTCH PPS final rule (84 FR 42399 through 42400; and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58859 through 58860). We are not proposing any changes to these policies in this proposed rule.

(2) Summary of Previously Adopted Minimum Numbers of Cases

The previously adopted minimum numbers of cases for these measures are set forth in the following table.

Table V.H-16: Previously Adopted Minimum Case Number Requirements for the FY 2024 Program Year and Subsequent Years

Measure Short Name	Minimum Number of Cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

f. Summary of Previously Adopted Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42400 through 42402), we finalized our proposal to use the same data to calculate the CDC NHSN HAI measures for the Hospital VBP Program that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020 for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402), we also finalized our proposal for the Hospital VBP Program to use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and to rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We are not proposing any changes to these policies in this proposed rule.

7. Extraordinary Circumstance Exception (ECE) Policy for the Hospital VBP Program

a. Background

(1) Previously Established Extraordinary Circumstance Exception (ECE) Policy Under the Hospital VBP Program

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50704 through 50707) for discussion of our Extraordinary Circumstance Exception (ECE) policy. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50704 through 50707), we adopted an ECE policy for the Hospital VBP Program, which recognized that there may be periods of time during which a hospital is affected by an extraordinary circumstance beyond its control. When adopting the policy, we stated that upon a hospital's request, we will consider providing an exception from the Hospital VBP Program requirements to hospitals affected by natural disasters or other extraordinary circumstances (78 FR 50704 through 50706). Specifically, we stated that we interpreted the minimum number of cases and measures requirement in sections 1886(o)(1)(C)(ii)(III) and (IV) of the Act to not include any measures or cases for which a hospital has submitted data during a performance period for which the hospital has been granted a Hospital VBP Program ECE. We expressed belief that this approach would help alleviate the reporting burden for a hospital that is adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the Hospital VBP Program.

On May 8, 2020, we published an Interim Final Rule with public comment

(IFC) titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' in response to the PHE for COVID–19 (hereafter referred to as the ''May 2020 IFC'') (85 FR 27550), where we modified the Hospital VBP Program's ECE policy to allow us to grant ECE exceptions to hospitals which have not requested them when we determine that an extraordinary circumstance that is out of their control, such as an act of nature (for example, a hurricane) or PHE (for example, the COVID–19 pandemic), affects an entire region or locale, in addition to retaining the individual ECE request policy (85 FR 27597 through 27598). We stated that if we grant an ECE to hospitals located in an entire region or locale under this revised policy and, as a result of granting that ECE, one or more hospitals located in that region or locale does not report the minimum number of cases and measures required to enable us to calculate a TPS for that hospital for the applicable program year, the hospital will be excluded from the Hospital VBP Program for the applicable program year. We also stated that a hospital that does not report the minimum number of cases or measures for a program year will not receive a two percent reduction to its base operating diagnosis-related group (DRG) payment amount for each discharge in the applicable program year and will also not be eligible to receive any value-based incentive payments for the applicable program year. We refer readers to sections V.H.6.d. and V.H.6.e. of the preamble of this proposed rule for the minimum number of measures and cases that we currently require hospitals to report in order to receive a TPS for a program year under the Hospital VBP Program.

(2) Extraordinary Circumstance Exception (ECE) Granted in Response to the PHE for COVID–19

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and VBP programs.[959] Specifically, we announced that we were granting ECEs for certain data reporting requirements and submission deadlines for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and VBP program.[960] For the Hospital VBP Program, we stated that qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures. The ECEs also relieved providers and facilities of their obligation to report HCAHPS survey data and CDC NHSN HAI data for the fourth quarter calendar year (CY) 2019, first quarter CY 2020, and second quarter CY 2020.

(3) Updated Application of the ECE Granted in Response to the PHE for COVID–19

On September 2, 2020, we published a separate IFC, titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (hereafter referred to as the ''September 2020 IFC'') (85 FR 54820). The September 2020 IFC updated the ECE we granted in response to the PHE for COVID–19, for the Hospital VBP Program and several other quality reporting programs (85 FR 54827 through 54838).

In the September 2020 IFC, we updated the ECE that we granted for the Hospital VBP Program (85 FR 54833 through 54835) and stated that we will not use any first or second quarter CY 2020 measure data that was voluntarily submitted for scoring purposes under the Hospital VBP Program. We expressed concern with the national comparability of the Hospital VBP Program data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19.

In the September 2020 IFC, we welcomed public comments on our policy to not use any first or second quarter CY 2020 measure data that was voluntarily submitted for scoring purposes under the Hospital VBP Program. We will respond to those public comments in the FY 2022 IPPS/LTCH PPS final rule.

8. Proposal To Revise Existing Code of Federal Regulations (CFR) Language by Replacing the Term ''System Administrator'' With the Term ''Security Official''

We are proposing to replace the term ''QualityNet System Administrator'' with ''QualityNet security official'' in § 412.167(b)(5) of our regulations. This update will align the terminology used for this program with the terminology we are proposing in section IX.A.8.c.(2). of this proposed rule to use for the Hospital IQR Program. This official is one of hospital's contact people for purposes of the appeal process under § 412.167(b).

We welcome public comment on this proposal to replace the term ''QualityNet System Administrator'' with ''QualityNet security official'' in our regulation text.

9. Proposal To Update References to QualityNet and Hospital Compare for the Hospital VBP Program

There are currently several codified requirements for the Hospital VBP Program in our regulations. However, we are proposing to update regulation text to reflect changes made to CMS resources. Specifically, we are proposing to revise regulations in two places:

- At 42 CFR 412.163 in paragraph (d) and at 42 CFR 412.164 at paragraph (b) to update the text to indicate that the *Hospital Compare* website is now available on the Care Compare site at: *https://www.medicare.gov/care-compare*.
- At 42 CFR 412.165 in paragraphs (c)(2) and (c)(4) to update the URL for our QualityNet website from *QualityNet.org* to *QualityNet.cms.gov*. We note that we launched the redesigned QualityNet website in November 2020.

We welcome public comment on this proposal to update references to CMS resources in our regulation text.

10. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall

[959] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[960] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital VBP Program.202F; We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule for details (85 FR 86193 through 86236).

11. References to Additional Requests for Information

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41472) for more information about how the Hospital VBP Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework. We refer readers to section IX.A of this proposed rule, where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard. We also refer readers to section IX.B of this proposed rule, where we request information on our Equity Plan for Improving Quality in Medicare, which outlines our commitment to closing the health equity gap through improved data collection to better measure and analyze disparities across programs and policies.

I. Hospital-Acquired Conditions (HAC) Reduction Program: Proposed Updates and Changes (42 CFR 412.170)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58860 through 58865).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Overview of Proposed Updates to the HAC Reduction Program and Requests for Information

In section IX.I.3.c. of this proposed rule, we propose to adopt a cross-program measure suppression policy and in section IX.I.3.d. we propose to suppress third and fourth quarter CY 2020 CMS PSI 90 and CDC NHSN HAI measure data from the HAC Reduction Program. In section IX.I.7. of this proposed rule, we clarify some aspects of the Extraordinary Circumstances Exception (ECE) policy. In section IX.I.9. of this proposed rule, we propose to revise our regulations for the HAC Reduction Program at 42 CFR 412.172(f)(4) to add the phrase ''or successor website'' to reflect the change in the CMS website name from *Hospital Compare* to *Care Compare.*

We also refer readers to section IX.B. of this proposed rule, Closing the Health Equity Gap in CMS Quality Programs—A Request for Information, where we request information on our Equity Plan for Improving Quality in Medicare, which outlines our commitment to closing the health equity gap through improved data collection to better measure and analyze disparities across programs and policies. The request for information asks for public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital equity score in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program.

We also refer readers to section IX.A. of this proposed rule where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section). This request for information supports our goal of moving fully to digital quality measurement in CMS quality reporting and value-based purchasing programs, including the HAC Reduction Program, by 2025.

3. Measures for FY 2022 and Subsequent Years

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports our goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework.

a. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we finalized the use of the CMS PSI 90 measure. These previously finalized measures, with their full measure names, are shown in this table.

HAC Reduction Program Measures for FY 2021 and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the *QualityNet* website at: *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html*. Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In this proposed rule, we are not proposing to add or remove any measures.

b. Measure Removal Factors Policy

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. In this proposed rule, we are not proposing any measure removal and retention factor policy changes.

c. Proposed Flexibility for Changes That Affect Quality Measures During a Performance or Measurement Period in the HAC Reduction Program

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE impedes effective quality measurement in many ways. Changes to clinical practices to accommodate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data used in quality measurement and the resulting quality scores. New clinical guidelines, diagnosis or procedure codes, and medications take time to be incorporated into quality measures, and once incorporated, those changes affect measure calculations. Additionally, COVID–19 prevalence is not identical across the country, meaning that the medical provider community has been affected differently at different times throughout the calendar year. Under those circumstances, we remain significantly concerned that quality measurement is distorted, which would result in skewed payment incentives and inequitable payments, particularly for hospitals or other providers that have treated more COVID–19 patients than others.

It is not our intention to penalize hospitals for performance on measures that are affected significantly by global events like the COVID–19 PHE. As previously discussed, the COVID–19 PHE had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including those that may result in HACs as measured by the HAC Reduction Program. As a result of the PHE, hospitals could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower payment adjustments in the HAC Reduction Program. We are also concerned that regional and temporal differences in COVID–19 prevalence during the FY 2022 and FY 2023 performance periods, which include data collected during the PHE, may directly affect hospitals' HAC measure performance for the FY 2022 and FY 2023 program years. Although these regional and temporal differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by hospitals, they directly affect the value-based payment adjustments that these hospitals are eligible to receive and could result in an unfair and inequitable distribution of those assessment of penalties for excess hospital acquired conditions. These inequities could be especially pronounced for hospitals that have treated a large number of COVID–19 patients.

Therefore, we are proposing to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress a number of measures from the FY 2022 and FY 2023 Total HAC Score calculations for the HAC Reduction Program if we determine that circumstances caused by the PHE for COVID–19 have affected these measures and the resulting Total HAC Scores significantly. Under this proposed policy, if we determine that the suppression of a HAC Reduction Program measure is warranted for a

program year, we would propose to calculate measure rates for that program year but then suppress the use of those rates to generate Total HAC Scores. We would instead assign each hospital a 0% weight for any suppressed measures in the Total HAC Score calculation. We would also provide confidential feedback reports to hospitals on their FY 2022 and FY 2023 performance to ensure that they are made aware of the changes in performance rates that we have observed. We would also publicly report the FY 2022 and FY 2023 data with appropriate caveats noting the limitations of the data due to the PHE for COVID–19.

In developing this proposed policy, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program. We believe that significant deviation in measured performance that can be reasonably attributed to a PHE is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we believe that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 PHE, we believe that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also note that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we believe that, as evidenced during the COVID–19 PHE, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress HAC Reduction Program measures for one or more program years that overlap with the PHE for COVID–19. We are proposing to adopt these Measure Suppression Factors for use in the HAC Reduction Program, and for consistency, the following other value-based purchasing programs: Hospital Value-Based Purchasing, Hospital Readmissions Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and End-Stage Renal Disease Quality Incentive Program. We believe that these Measure Suppression Factors will help us evaluate the HAC Reduction Program's measures and that their adoption in the other value-based purchasing programs, as previously noted, will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are:

1. Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

2. Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.

3. Rapid or unprecedented changes in:

i. Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or

ii. the generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

4. Significant national shortages or rapid or unprecedented changes in: (i) Healthcare personnel; (ii) medical supplies, equipment, or diagnostic tools or materials; or (iii) patient case volumes or facility-level case mix.

We also considered alternatives to this proposed policy that could fulfill our objective to not hold facilities accountable for distorted measure results under the FY 2022 and FY 2023 Programs. As previously noted, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, CMS issued a nationwide, blanket ECE for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the COVID–19 PHE. This blanket ECE waived all data reporting requirements for Q1 and Q2 2020 data, including waiving the use of claims data and data collected through the CDC's web-based surveillance system for this data period. Quality data collection resumed on July 1, 2020. This blanket ECE is likely to affect our quality programs significantly, especially in future years as CY 2020 measurement forms the basis for performance assessments in our value-based purchasing programs. We considered extending the blanket ECE that we issued for Q1 and Q2 2020 for Q3 and Q4 2020. This alternative would protect providers and suppliers from having their quality data used for quality scoring purposes while those data are likely to have been affected significantly by the PHE for COVID–19. However, this option would leave no comprehensive data available for us to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

As an alternative to the proposed quality measure suppression policy, we also considered not making any further changes to the Program or measures and using Q3 and Q4 2020 quality measurement data that we previously specified for the HAC Reduction Program. However, this alternative would mean assessing hospitals and other providers and suppliers using quality measure data that could be affected significantly by the COVID–19 PHE. Additionally, given the geographic disparities in the COVID–19 PHE's effects, implementation of the FY 2022 and FY 2023 HAC Reduction Programs as previously finalized would place hospitals in regions that were more heavily affected by the pandemic in Q3 and Q4 of 2020 at a disadvantage compared to hospitals in regions that were more heavily affected during the first two quarters of CY 2020, for which we are not using HAC Reduction Program data to calculate the Program's measures.

We view this measure suppression proposal as necessary to ensure that the FY 2022 and FY 2023 HAC Reduction Programs do not reward or penalize facilities based on factors that the Program's measures were not designed to accommodate. We intend for this proposed policy to provide short-term relief to hospitals when we have determined that one or more of the Measure Suppression Factors warrants the suppression of one or more of the HAC Reduction Program's measures.

We invite public comments on this proposal for the adoption of a measure suppression policy for the FY 2022 and FY 2023 HAC Reduction Program years, as previously described, and also on the proposed Measure Suppression Factors that we have developed for purposes of this proposed policy.

We are also inviting comment on whether we should consider adopting a measure suppression policy that would apply in a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress certain measures without specifically proposing to do so in rulemaking. We also request comment on whether we should in future years consider adopting

any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, the COVID–19 PHE affected different regions of the country at different rates depending on factors like time of year, geographic density, State and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also request commenters' feedback on whether we should, rather than suppress a measure completely, consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

d. Proposal To Suppress Third and Fourth Quarter CY 2020 Data From the FY 2022 and FY 2023 HAC Reduction Program

In section IX.I.3.c., we proposed to adopt a measure suppression policy. We are proposing to suppress the third and fourth quarters of CY 2020 (that is, July 1, 2020 through September 30, 2020 (Q3 2020) and October 1, 2020 through December 31, 2020 (Q4 2020)) CDC NHSN HAI and CMS PSI 90 data from our performance calculations for FY 2022 and FY 2023 under the proposed Measure Suppression Factor (1) ''significant deviation in national performance on the measure, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years;'' and the Measure Suppression Factor (4) subfactor, ''significant national or regional shortages or rapid or unprecedented changes in patient case volumes or case mix.'' Although Q3 and Q4 2020 data would be suppressed from the Total HAC Score calculation, hospitals would still be required to submit such data and such data would be used for public reporting purposes.

As described in more detail in section IX.B.7.a., through memoranda released in March 2020 and an IFC published in September 2020 (85 FR 54827 through 54828), in response to the COVID–19 PHE, we excluded, by application of our ECE policy, all data submitted regarding care provided during the first and second quarters of CY 2020 from our performance calculations for FY 2022 and FY 2023. We excluded such data because of our concerns about the national comparability of these data due to the geographic differences of COVID–19 incidence rates and hospitalizations, along with different impacts resulting from different State and local laws and policy changes implemented in response to COVID–19.

We continue to be concerned about measure performance and the national comparability of such performance during Q3 and Q4 2020 and are therefore proposing to suppress Q3 2020 and Q4 2020 HAI and CMS PSI 90 measure data from the calculation of the Total HAC Score. An analysis performed by the CDC found that CLABSI, CAUTI, and MRSA had statistically significant measure rate increases during Q3 and Q4 CY 2020 as compared to Q3 and Q4 CY 2019. We believe that the measure data may have been distorted due to circumstances unique to the effects of the COVID–19 PHE, such as staffing shortages and turnover, patients that are more susceptible to infections due to increased hospitalization stays, and longer indwelling catheters and central lines. As for the SSI and CDI measures, neither measure had a statistically significant increase or decrease during Q3 and Q4 2020 as compared to Q3 and Q4 2019. For the SSI measure, the low reporting volume is due to the decrease in surgeries during the COVID–19 PHE, while the CDI measure has historically been declining. Though the COVID–19 PHE may not have the same clinical impact on the SSI and CDI measures, we believe that due to the low reporting volume of these two measures and for maintaining consistency of the full CDC NHSN HAI measure set, all five CDC NHSN HAI measures should be suppressed instead of just three of them. Similarly, our analysis of CMS PSI 90 measure suggested that comparability of performance on the measure has also been impacted by the PHE. Our analysis found a decrease in volume across all component Patient Safety Indicator (PSI) measures, especially those related to elective surgeries (postoperative acute kidney injury rate, postoperative respiratory failure rate, and postoperative sepsis rate). Our analysis also found increased risk-adjusted rates for patients with COVID–19 compared to patients without COVID–19 as well as increased risk-adjusted rates for the three component PSI measures that include non-surgical patients (pressure ulcer rate, iatrogenic pneumothorax rate, and in-hospital fall with hip fracture rate) while the surgical-specific component PSI measures (perioperative hemorrhage and hematoma rate, postoperative acute kidney injury rate, postoperative respiratory failure rate, perioperative pulmonary embolism or deep vein thrombosis rate, postoperative sepsis rate, postoperative wound dehiscence rate, and unrecognized abdominopelvic accidental puncture/laceration rate) did not see substantial change in risk-adjusted rates.

As previously noted, under this policy, participating hospitals would continue to report all HAC Reduction Program measures' data to CMS, and in the case of the CDC NHSN HAI measures, to CDC, so that we can monitor the effect of the circumstances on quality measurement and determine appropriate policies in the future. We would also use Q3 and Q4 2020 data in feedback reports to hospitals as part of program activities, including to inform their quality improvement activities, and to ensure that they are made aware of and have an opportunity to preview the changes in performance rates we observe and display via public reporting to ensure transparency.

The proposed suppression of Q3 and Q4 2020 HAI and CMS PSI 90 measure data would result in the following applicable periods for calculating Total HAC Scores for FY 2022 and FY 2023 HAC Reduction Programs. For the FY 2022 HAC Reduction Program, the applicable period used for scoring for the CMS PSI 90 measure would remain the same as resulted from the previously granted ECE, that is, the 18-month period from July 1, 2018 through December 31, 2019. For the CDC NHSN HAI measures, this further exclusion would result in an applicable period for FY 2022 of the 12-month period from January 1, 2019 through December 31, 2019. For the FY 2023 HAC Reduction Program, the exclusion would result in a shortened applicable period, for the CMS PSI 90 measure, to the 12-month period from July 1, 2019 through December 31, 2019 and January 1, 2021 through June 30, 2021, and for the CDC NHSN HAI measures to the 12-month period from January 1, 2021 through December 31, 2021.

We believe using data from the proposed periods will provide sufficiently reliable data for evaluating hospital performance that we can use for FY 2022 and FY 2023 scoring. In the FY 2017 IPPS/LTCH PPS final rule, we clarified that a hospital has complete data for the CMS PSI 90 measure if it has 12 months or more of data and three or more eligible discharges for at least one component PSI measure within the CMS PSI 90 composite measure (81 FR 50712). Further, as we have previously noted, NQF has determined that the CMS PSI 90 measure is reliable using 12 months of data (81 FR 57021). We have also determined that a 12-month performance period provides us with

sufficient data on which to score hospital performance on NHSN measures in the Safety domain of the Hospital VBP Program (79 FR 50071). We also note that 12-month performance periods are consistent with the reporting periods used for these measures under the Hospital VBP Program (79 FR 50071) and when the measures were previously in the Hospital IQR Program (78 FR 50689).

In determining how to address the impact of the COVID–19 PHE on hospital performance and calculating Total HAC Scores for FY 2022 and FY 2023, we also considered as an alternative to suppressing all Q3 and Q4 2020 data, suppressing CDC NHSN HAI measure data while using the CMS PSI 90 measure data. This alternative would have focused on suppressing those measures most impacted by the COVID–19 PHE. However, as previously discussed, we still have concerns about the comparability of data for the CMS PSI 90 measure from Q3 and Q4 2020 due to differences in the risk-adjusted rate of component PSI measures for COVID-positive patients. In addition, an analysis revealed that smaller and rural hospitals would be more negatively impacted by this approach.

We also considered making no modifications to the program and suppressing no measure data from Q3 and Q4 2020 for assessing FY 2022 and FY 2023 Total HAC Scores as an additional alternative to using the measure suppression policy. As discussed, when considering this previously discussed approach, this alternative would be operationally easier to implement, but would mean assessing participating hospitals using quality measure data that has been impacted by the COVID–19 PHE without additional adjustments to the measure. Additionally, given the geographic disparities in the COVID–19 PHE's effects, this policy could place hospitals in regions that were hit harder by the pandemic in Q3 and Q4 of 2020 at a disadvantage compared to hospitals in regions that were more heavily affected earlier in CY 2020. Ultimately, we believe that our proposal to suppress both CDC NHSN HAI and CMS PSI 90 measure data from Q3 and Q4 2020 more fairly addresses the impact of the COVID–19 PHE on participating hospitals.

We invite comments on our proposal to suppress third and fourth quarter CY 2020 CDC NHSN HAI and CMS PSI 90 measure data from the HAC Reduction Program.

4. HAC Reduction Program Scoring Methodology and Scoring Review and Corrections Period

In FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we adopted the Equal Measure Weights approach to scoring and clarified the Scoring Calculations Review and Correction Period (83 FR 41484) for the HAC Reduction Program. Hospitals must register for a *QualityNet* website's secure portal account in order to access their annual hospital-specific reports. We will continue using this scoring methodology and the Scoring Calculations Review and Correction Period process in FY 2021 and for subsequent years. In this proposed rule, we are not proposing any changes to the HAC Reduction Program scoring methodology or Scoring Calculations Review and Corrections Period.

5. Validation of HAC Reduction Program Data

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program, because the Hospital IQR Program finalized its proposals to remove CDC NHSN HAI measures from its program. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), we provided additional clarification to the validation selection and scoring methodology. We also refer readers to the *QualityNet* website for more information regarding chart-abstracted data validation of measures. In the FY 2020 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy to align the HAC Reduction Program validation process with that of the Hospital IQR Program. Specifically, we aligned the hospital selection and submission quarters beginning with FY 2024 Hospital IQR and HAC Reduction Programs validation so that we only require one pool of hospitals to submit data for validation. Additionally, we finalized a policy requiring hospitals to submit digital files when submitting medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), we finalized our policy that for the FY 2024 program year and subsequent years, we will use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program, which must be reported using the following validation schedule.

Finalized Validation Period for the HAC Reduction Program in FY 2024
[*Dates are subject to change]

Discharge Quarters by Fiscal Year (FY)	Current CDC NHSN HAI Submission Deadline*	Current CDC NHSN HAI Validation Templates*	Estimated CDAC[961] Record Request	Estimated Date Records Due to CDAC	Estimated Validation Completion
Q1 2021	08/15/2021	08/01/2021	08/30/2021	09/29/2021	12/15/2021
Q2 2021	11/15/2021	11/01/2021	11/29/2021	12/29/2021	03/15/2022
Q3 2021	02/15/2022	02/01/2022	02/28/2022	03/30/2022	06/15/2022
Q4 2021	05/15/2022	05/01/2022	05/30/2022	06/29/2022	09/15/2022

We are not proposing any changes to the policies regarding measure validation in this proposed rule.

6. Overall Hospital Quality Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Ratings (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that

[961] The CMS Clinical Data Abstraction Center (CDAC) performs the validation.

are publicly reported on a CMS website, including data from the HAC Reduction Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule for details.

7. Extraordinary Circumstances Exception (ECE) Policy for the HAC Reduction Program

a. Background

(1) Previously Established Extraordinary Circumstance Exception (ECE) Policy Under the HAC Reduction Program

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581) and the FY 2018 IPPS/LTCH PPS (82 FR 38276 through 38277) for discussion of our Extraordinary Circumstances Exception (ECE) policy. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581), we adopted an ECE policy for the HAC Reduction Program, which recognized that there may be periods of time during which a hospital is affected by an extraordinary circumstance beyond its control. When adopting the policy, we noted that we considered the feasibility and implications of excluding data for certain measures for a limited period of time from the calculations for a hospital's measure results or Total HAC Score for the applicable performance period. By minimizing the data excluded from the program, the proposed policy enabled affected hospitals to continue to participate in the HAC Reduction Program for a given fiscal year if they otherwise continued to meet applicable measure minimum threshold requirements. We expressed the belief that this approach would help alleviate the burden for a hospital that might be adversely impacted by a natural disaster or other extraordinary circumstance beyond its control, while enabling the hospital to continue to participate in the HAC Reduction Program. In developing this policy, we considered a policy and process similar to that for the Hospital IQR Program, as finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), modified by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836) (designation of a non-CEO hospital contact), and further modified in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) (amended § 412.40(c)(2)) to refer to ''extension or exemption'' instead of the former ''extension or waiver''). We also considered how best to align an extraordinary circumstance exception policy for the HAC Reduction Program with existing extraordinary circumstance exception policies for other IPPS quality reporting and payment programs, such as the Hospital Value-Based Purchasing (VBP) Program, to the extent feasible.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38277), we modified the requirements for the HAC Reduction Program ECE policy to further align with the process used by other quality reporting and value-based purchasing programs for requesting an exception from program reporting due to an extraordinary circumstance not within a provider's control.

(2) Extraordinary Circumstances Exception (ECE) Granted in Response to the COVID–19 Public Health Emergency

On March 22, 2020, in response to COVID–19, we announced relief for clinicians, providers, hospitals, and facilities participating in Medicare quality reporting and value-based purchasing programs.[962] Specifically, we announced that we were granting ECEs for certain data reporting requirements and submission deadlines for the first and second quarters of CY 2020. On March 27, 2020, we published a supplemental guidance memorandum that described the scope and duration of the ECEs we were granting under each Medicare quality reporting and value-based purchasing program.[963] In that memorandum, we stated that qualifying claims would be excluded from the measure calculations for the CMS PSI 90 for the first and second quarters of calendar year (CY) 2020. The ECEs also relieved providers and facilities of their obligation to report CDC NHSN HAI data for the fourth quarter calendar year (CY) 2019, first quarter CY 2020 and second quarter CY 2020.

(3) Updated Application of the ECE Granted in Response to the COVID–19 PHE

On September 2, 2020, we published the Interim Final Rule with comment period (IFC), ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54820). The IFC updated the ECE we granted in response to the PHE for COVID–19, for the HAC Reduction Program and several other quality reporting programs (85 FR 54827 through 54838).

In the IFC, we updated the previously announced application of our ECE policy for the HAC Reduction Program (85 FR 54830 through 54832) to the COVID–19 PHE to exclude any CDC NHSN HAI data submitted regarding care provided during first and second quarter of CY 2020 from our calculation of performance for FY 2022 and FY 2023, even if optionally reported. We recognized that the chart-abstracted measures in the HAC Reduction Program are calculated based on data submitted to the CDC's NHSN and that because the CDC uses the same data for epidemiological surveillance, hospitals may have reporting requirements which are not affected by our ECE (for example, State requirements). We expressed concern with the national comparability of the HAC Reduction Program data due to the geographic differences of COVID–19 incidence rates and hospitalizations along with different impacts resulting from different State and local law and policy changes implemented in response to COVID–19.

In the IFC, we welcomed public comments on our policy to exclude any data submitted regarding care provided during the first and second quarter of CY 2020 from our calculation of performance for the FY 2022 and FY 2023 program years. We will respond to those public comments in the FY 2022 IPPS/LTCH PPS final rule.

In the September 2, 2020 IFC, we also announced that if due to ECEs related to the COVID–19 PHE, we do not have enough data to reliably measure national performance, we may propose to not score hospitals based on such limited data or make the associated payment adjustments to hospitals under the IPPS for the affected program year. We stated that, if circumstances warranted, we could propose to suspend prospective application of program penalties or payment adjustments through the annual IPPS/LTCH PPS proposed rule. We also stated that, in the interest of time and transparency, we may provide subregulatory advance notice of our intentions to suspend such penalties and adjustments through routine communication channels to facilities, vendors, and QIOs. The communications could include memos, emails, and notices on the public

[962] CMS, Press Release, CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID–19 (Mar. 22, 2020), *https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting.*

[963] CMS, Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19 (Mar. 27, 2020), *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

QualityNet website (*https://www.qualitynet.cms.gov/*).[964]

In section IX.I.3.d., as previously mentioned, we propose to suppress third and fourth quarter CY 2020 data from FY 2022 and FY 2023 Total HAC Scores using the measure suppression policy proposed in IX.I.3.c.

b. General Clarifications to HAC Reduction Program ECE Policy

After the nationwide ECE granted in response to the COVID–19 PHE ended, we received several requests from hospitals for individual ECEs under the HAC Reduction Program, due to extraordinary circumstances resulting from the continuing impact of the pandemic. These individual ECE requests specifically requested clarity on whether CDC NHSN HAI measure data that hospitals submitted to the CDC NHSN because of State reporting requirements could be excluded from the HAC Reduction Program Total HAC Score calculations. In this proposed rule, we would like to clarify that an ECE granted under the HAC Reduction Program may allow an exception from quality data reporting requirements and/or may grant a request to exclude any data submitted (whether submitted for claims purposes or to the CDC NHSN) from the calculation of a hospital's measure results or Total HAC Score for the applicable period, depending on the exact circumstances under which the request was made.

We have also received a few ECE requests from hospitals for an exception from the HAC Reduction Program payment reduction. The ECE policy for the HAC Reduction Program is intended to provide relief for a hospital that has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the hospital's control by excluding data and/or granting an exception with respect to data reporting requirements for the period during which performance or ability to submit data was impacted. However, we also believe that the hospital should still be evaluated for the remainder of the applicable period during which performance and/or ability to timely submit data was not impacted (to the extent that enough data are available to ensure that the calculation is statistically sound). This policy is not intended to extend to payment reductions. Therefore, we would like to clarify that an approved ECE for the HAC Reduction Program does not exempt hospitals from payment reductions under the HAC Reduction Program.

c. Clarification of the Impact of ECE Excluded Data for the HAC Reduction Program

In this proposed rule, we would also like to clarify the impact on upcoming HAC Reduction Program calculations of data excluded from the HAC Reduction Program due to the nationwide ECE. In order to determine and evaluate what kind of impact the PHE for COVID–19 might have on the HAC Reduction Program, we conducted analyses to simulate the impact of an altered performance period on program eligibility and the resulting payment impacts to hospitals using data for the FY 2020 HAC Reduction Program performance period. This analysis was intended to evaluate what patterns we might observe in HAC Reduction Program eligibility and payment as a result of excluding 6 months of data due to the ECE granted in response to the PHE for COVID–19. Our analysis found that when 6 months of data are removed from HAC Reduction Program calculations, 12.2 percent of hospitals see a change in worst-performing quartile status, with 6.1 percent moving into the worst-performing quartile and 6.1 percent moving out. For context, in a typical year approximately 18 percent of hospitals experience a change in worst-performing quartile status from one year to the next. We are performing additional analyses as CY 2020 data becomes available, and we will provide updated analyses as necessary when it becomes available.

As we stated in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101) and reiterated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41475), we will use a subregulatory process to make nonsubstantive updates to measure specifications to facilitate the program's operation when minor changes are required, but do not substantively impact the program's previously finalized policies (84 FR 42385 through 42387). We believe that updates to measure inclusion criteria proposed by the measure developers in response to the COVID–19 PHE are nonsubstantive and do not substantially impact the HAC Reduction Program's previously finalized policies. For more details, we refer readers to the Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hac/reports*.

8. Proposed Regulatory Updates (42 CFR 412.172)

We are proposing to update the references to CMS resources in regulation text. We note that we renamed our *Hospital Compare* website. It is now referred to as *Care Compare* and is available at: *https://www.medicare.gov/care-compare*. We are proposing to revise our regulations for the HAC Reduction Program at 42 CFR 412.172(f)(4) to reflect the new website name. We propose to amend § 412.172(f)(4), by adding the phrase ''or successor website'' so that the text reads ''Hospital Compare website or successor website.'' [965] We invite public comment on our proposal.

J. Proposed Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient

[964] We note that the QualityNet website (previously at *QualityNet.org*) has transitioned to a new uniform resource locator (URL) at *QualityNet.cms.gov*.

[965] While the statute refers to *Hospital Compare,* the name has been changed to *Care Compare.* Now called *Care Compare,* the website continues to serve the purpose of displaying quality data submitted for the HAC Reduction Program.

care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

The Affordable Care Act made a number of statutory changes relating to the determination of a hospital's FTE resident limit for direct GME and IME payment purposes and the manner in which FTE resident limits are calculated and applied to hospitals under certain circumstances. Section 5503(a)(4) of the Affordable Care Act added a new section 1886(h)(8) to the Act to provide for the reduction in FTE resident caps for direct GME under Medicare for certain hospitals training fewer residents than their caps, and to authorize the redistribution of the estimated number of excess FTE resident slots to other qualified hospitals. In addition, section 5503(b) amended section 1886(d)(5)(B)(v) of the Act to require the application of the section 1886(h)(8) of the Act provisions in the same manner to the IME FTE resident caps. The policy implementing section 5503 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72147 through 72212) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53424 through 53434). Section 5506(a) of the Affordable Care Act amended section 1886(h)(4)(H) of the Act to add a new clause (vi) that instructs the Secretary to establish a process by regulation under which, in the event a teaching hospital closes, the Secretary will permanently increase the FTE resident caps for hospitals that meet certain criteria up to the number of the closed hospital's FTE resident caps. The policy implementing section 5506 of the Affordable Care Act was included in the November 24, 2010 CY 2011 OPPS/ASC final rule with comment period (75 FR 72212 through 72238), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434 through 53448), and the FY 2015 IPPS/LTCH final rule (79 FR 50122–50140).

2. Provisions of the Consolidated Appropriations Act, 2021

The Consolidated Appropriations Act, 2021 (CAA), division CC, contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions (but not more than 200 new positions for a fiscal year), to be distributed beginning in fiscal year 2023, with priority given to hospitals in 4 statutorily-specified categories. Section 127 of the CAA makes statutory changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track (RTT), and the 3-year rolling average set out at section 1886(h)(4)(G)(i) of the Act used to calculate payments for these hospitals. Section 131 of the CAA makes statutory changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration. We provide detailed proposals for implementing these three CAA provisions in this rule.

a. Distribution of Additional Residency Positions Under the Provisions of Section 126 of Division CC of the Consolidated Appropriations Act, 2021 (CAA)

(1) Overview

Section 126(a) of the CAA amended section 1886(h) of the Act by adding a new section 1886(h)(9) requiring the distribution of additional residency positions to qualifying hospitals. Section 1886(h)(9)(A) requires that for FY 2023, and for each succeeding fiscal year until the aggregate number of full-time equivalent (FTE) residency positions distributed is equal to 1,000, the Secretary shall initiate separate rounds of applications from hospitals for these additional residency positions. The Secretary is required, subject to certain provisions in the law, to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by the number of positions that may be approved by the Secretary for that hospital. The Secretary is required to notify hospitals of the number of positions distributed to them by January 31 of the fiscal year of the increase, and the increase is effective beginning July 1 of that fiscal year. Section 1886(h)(9)(A) also limits the aggregate number of such positions made available in a single fiscal year across all hospitals to no more than 200.

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(9)(B) of the Act requires the Secretary to take into account the demonstrated likelihood of the hospital filling the positions made available within the first five training years beginning after the date the increase would be effective, as determined by the Secretary.

Section 1886(h)(9)(B) also requires a minimum distribution for certain categories of hospitals. Specifically, the Secretary is required to distribute at least 10 percent of the aggregate number of total residency positions available to each of four categories of hospitals. Stated briefly, and discussed in greater detail later in this proposed rule, the categories are as follows: (1) Hospitals located in rural areas or that are treated as being located in a rural area (pursuant to sections 1886(d)(2)(D) and 1886(d)(8)(E) of the Act); (2) hospitals in which the reference resident level of the hospital is greater than the otherwise applicable resident limit; (3) hospitals in states with new medical schools or additional locations and branches of existing medical schools; and (4) hospitals that serve areas designated as Health Professional Shortage Areas (HPSAs). Section 1886(h)(9)(F)(ii) of the Act defines a qualifying hospital as a hospital in one of these four categories.

Section 1886(h)(9)(C) of the Act places certain limitations on the distribution of the residency positions. First, a hospital may not receive more than 25 additional FTE residency positions. Second, no increase in the otherwise applicable resident limit of a hospital may be made unless the

hospital agrees to increase the total number of FTE residency positions under the approved medical residency training program of the hospital by the number of positions made available to that hospital.

(2) Determinations Required for the Distribution of Residency Positions

(a) Determination That a Hospital has a Demonstrated Likelihood of Filling the Positions

Section 1886(h)(9)(B)(i) of the Act directs the Secretary to take into account the demonstrated likelihood of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary. Section 1886(h)(9)(A)(iii)(II) of the Act requires that the increase would be effective beginning July 1 of the fiscal year of the increase. For FY 2023, this means the additional positions would be effective July 1, 2023.

As discussed later in this section, we are proposing that the application deadline for the additional positions available for a fiscal year be January 31 of the prior fiscal year. Accordingly, for FY 2023, all references in section V.J.2.a of this proposed rule to the application deadline are references to the proposed application deadline of January 31, 2022. We are proposing that a hospital would show a demonstrated likelihood of filling the additional positions (sometimes equivalently referred to as slots) for which it applies by demonstrating that it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program.

In order to demonstrate that it does not have sufficient room under its current FTE resident cap(s), we are proposing that a hospital submit copies of its most recently submitted Worksheets E, Part A and E–4 from the Medicare cost report CMS-Form-2552–10) as part of its application for an increase to its FTE resident cap.

We are proposing that a hospital demonstrate and attest to a planned new program or expansion of an existing program by meeting at least one of the following two criterion:

• *Demonstrated Likelihood Criterion 1 (New Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs as part of a new residency program that it intends to establish on or after the date the increase would be effective (that is, a new program that begins training residents at any point within the hospital's first five training years beginning on or after the date the increase would be effective). Under Demonstrated Likelihood Criterion 1, the hospital would be required to check at least one of the following as part of its application:

☐ Application for approval of the new residency program has been submitted to the ACGME or the American Board of Medical Specialties (ABMS) by the application deadline for that year.

☐ The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval of the new program by the application deadline for that year.

☐ The hospital has received written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

• *Demonstrated Likelihood Criterion 2 (Expansion of an Existing Residency Program).* The hospital does not have sufficient room under its FTE resident cap, and the hospital intends to use the additional FTEs to expand an existing residency training program within the hospital's first five training years beginning on or after the date the increase would be effective. Under Demonstrated Likelihood Criterion 2, the hospital would be required to check at least one of the following as part of its application:

☐ The hospital has approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

☐ The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.Under Demonstrated Likelihood Criterion 2, the hospital would be applying for an increase in its FTE resident cap because it is expanding an existing residency program. We are proposing this means that as of the application deadline the hospital is either already training residents in this program, or, if the program exists at another hospital as of that date, the residents begin to rotate at the applying hospital on or after the effective date of the increase.We note that section 1886(h)(9)(C)(ii) of the Act requires that if a hospital is awarded positions, that hospital must increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on the newly awarded positions under section 126 of CAA. We are proposing that a hospital must, as part of its application, attest to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased based on any newly awarded positions.

(b) Determination of Hospitals That Are Located in a Rural Area or Are Treated as Being Located in a Rural Area (Category One)

Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute not less than 10 percent of resident positions available for distribution to each of four categories of hospitals. Under section 1886(h)(9)(B)(ii)(I) of the Act, the first of these categories consists of hospitals that are located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. We refer to this category as Category One.

Section 1886(d)(2)(D)(ii) of the Act defines a rural area as any area outside a Metropolitan Statistical Area (MSA). Under the existing regulations at § 412.64(b)(1)(ii), an ''urban area'' means an MSA or a Metropolitan Division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by the Executive Office of Management and Budget. Under existing § 412.64(b)(1)(ii)(C), a ''rural area'' means any area outside an urban area. Since FY 2005, we no longer use the term MSA, but instead use the term Core-Based Statistical Area (CBSA). Certain CBSAs are designated as urban, while those not designated as urban are considered rural. For purposes of Section 1886(h)(9)(B)(ii), we are proposing that a hospital with its main campus located in an area outside of an urban CBSA is a rural hospital. We note that this definition of ''rural area'' is consistent with our policy concerning designation of rural areas for wage index purposes.

Similar to our historical wage index policy of crosswalking counties to CBSAs as discussed in section III.A.4. of this proposed rule, CMS is proposing to use the County to CBSA Crosswalk and Urban CBSAs and Constituent Counties for Acute Care Hospitals File, or successor files containing similar information, from the most recent FY IPPS final rule (or correction notice if applicable) to determine if a hospital is a rural hospital. (This file would be available on the CMS website in

approximately August of the year prior to the year of the application deadline. Under the file's current format, blank cells in Columns F and G indicate an area outside of a CBSA.)

Under section 1886(d)(8)(E) of the Act, a subsection (d) hospital (that is, generally, an IPPS hospital) that is physically located in an urban area is treated as being located in a rural area for purposes of payment under the IPPS if it meets criteria specified in section 1886(d)(8)(E)(ii) of the Act, as implemented in the regulations at § 412.103. Under these regulations, a hospital may apply to CMS to be treated as located in a rural area for purposes of payment under the IPPS.Given the fixed number of available residency positions, it is necessary to establish a deadline by which a hospital must be treated as being located in a rural area for purposes of Category One. We are proposing to use Table 2, or a successor table containing similar information, posted with the most recent IPPS final rule (or correction notice if applicable) to determine whether a hospital is reclassified to rural under § 412.103. If a hospital is not listed as reclassified to rural on Table 2, but has been subsequently approved by the CMS Regional Office to be treated as being located in a rural area for purposes of payment under the IPPS as of the application deadline for additional positions for the fiscal year, we are proposing that the hospital must submit its approval letter with its application in order to be treated as being located in a rural area for purposes of Category One.

(c) Determination of Hospitals for Which the Reference Resident Level of the Hospital Is Greater Than the Otherwise Applicable Resident Limit (Category Two)

Under section 1886(h)(9)(B)(ii)(II), the second category consists of hospitals in which the reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii)) is greater than the otherwise applicable resident limit. We refer to this category as Category Two.

Under section 1886(h)(9)(F)(iii), the term 'reference resident level' means, with respect to a hospital, the resident level for the most recent cost reporting period of the hospital ending on or before the date of enactment of section 1886(h)(9), December 27, 2020, for which a cost report has been settled (or, if not, submitted (subject to audit)), as discussed in this proposed rule.

Under section 1886(h)(9)(F)(iii), the term 'resident level' has the meaning given such term in paragraph (7)(C)(i). That section defines ''resident level'' as with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

Under section 1886(h)(9)(F)(i), the term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to the changes made by this provision of CAA 2021, but taking into account section 1886(h)(7)(A), (7)(B), (8)(A), and (8)(B) of the Act. These paragraphs all address the distribution of positions and redistribution of unused positions.

In the CY 2011 OPPS final rule, we previously interpreted these terms when we implemented section 5503 of the Affordable Care Act. Under section 1886(h)(8)(H)(i) (as interpreted in the CY 2011 OPPS final rule (75 FR 46391)), the ''reference resident level'' generally refers to the number of unweighted allopathic and osteopathic FTE residents who are training at a hospital in a given cost reporting period. That is, the ''reference resident level'' refers to a hospital's allopathic and osteopathic FTE resident count for a specific period. The definition can vary based on what calculation is being performed to determine the correct allopathic and osteopathic FTE resident count (see, for example, 42 CFR 413.79(c)(1)(ii)). As noted previously, section 126 of the CAA, under new section 1886(h)(9)(F)(iii) defines the ''reference resident level'' as coming from the most recent cost reporting period of the hospital ending on or before the date of enactment of the CAA (that is, December 27, 2020).

Under new section 1886(h)(9)(F)(i), the term ''otherwise applicable resident limit'' is defined as ''the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraphs (7)(A), (7)(B), (8)(A), and (8)(B).'' We propose to define this as the hospital's 1996 cap during its reference year, adjusted for the following: New programs as defined at § 413.79(e); participation in a Medicare GME affiliation agreement as defined at §§ 413.75(b) and 413.79(f); participation in an Emergency Medicare GME affiliation agreement as defined at § 413.79(f); participation in a hospital merger; whether an urban hospital has a separately accredited rural training track program as defined at § 413.79(k); applicable decreases or increases under section 422 of the MMA, applicable decreases or increases under section 5503 of the Affordable Care Act, and applicable increases under section 5506 of the Affordable Care Act.

Regarding the term 'resident level', in the CY 2011 OPPS final rule (75 FR 46391) we indicated that we generally refer to a hospital's number of unweighted allopathic and osteopathic FTE residents in a particular period as the hospital's resident level, which we propose to define consistently with the definition in section 126 of the CAA; that is, the ''resident level'' under section 1886(h)(7)(c)(i), which is defined as the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

For the purposes of section 126 of the CAA we are proposing that the definitions of the terms ''otherwise applicable resident level,'' ''reference resident level,'' and ''resident level'' be as similar as possible to the definitions those terms have in the regulations at § 413.79(c) as developed in the CY 2011 OPPS rulemaking.

(d) Determination of Hospitals Located in States With New Medical Schools, or Additional Locations and Branch Campuses (Category Three)

The third category specified in section 1886(h)(9)(B)(ii) of the Act, as added by section 126 of CAA, consists of hospitals located in States with new medical schools that received 'Candidate School' status from the Liaison Committee on Medical Education (LCME) or that received 'Pre-Accreditation' status from the American Osteopathic Association (AOA) Commission on Osteopathic College Accreditation (the COCA) on or after January 1, 2000, and that have achieved or continue to progress toward 'Full Accreditation' status (as such term is defined by the LCME or toward 'Accreditation' status (as such term is defined by the COCA); or additional locations and branch campuses established on or after January 1, 2000, by medical schools with 'Full Accreditation' status (as such term is defined by LCME) or 'Accreditation' status (as such term is defined by the COCA). We note that the statutory language is specific with respect to these definitions. We refer to this category as Category Three.

Based on research and assistance received from LCME and the COCA, we understand that each accrediting body administers a multi-step processes for applicant medical schools to progress to

fully accredited status within the first few years after they are established and begin training students. LCME grants candidate status to an applicant medical education program after it reviews and approves the medical school's data collection instrument and planning self-study; at this point, it determines that the school is ready for a survey visit, and the preliminary accreditation survey visit is scheduled. After that visit, LCME reviews the survey team's preliminary survey report and determines whether or not sufficient progress toward compliance with accreditation standards has been made and satisfactory plans for the medical education program have been developed.

If LCME grants preliminary accreditation status, the school may begin accepting applications for enrollment. During the second year of the school's charter class, a school with preliminary accreditation status may submit information and receive a survey site visit to determine whether it meets criteria for provisional accreditation status. Finally, LCME grants full accreditation status to schools with provisional accreditation status, typically in the fourth teaching year, after determining the school is in compliance with or has made significant progress toward attaining compliance with all full accreditation standards.

LCME defines a regional campus, comparable to ''additional locations and branch campuses'' in Section 1886(h)(9)(B)(ii)(III)(bb) of the Act, as a site distinct from the main campus of the medical school where students spend at least one full year of the curriculum. Regional campuses of a medical education program receive accreditation status through the main campus of the program and are not separately accredited.

The COCA may grant pre-accreditation status to a proposed college of osteopathic medicine (COM) that has achieved candidate status and meets the standards of pre-accreditation status. The pre-accreditation process starts with the submission of a pre-accreditation self-study by a proposed COM; COCA staff then reviews the submission and conducts a site visit to examine the proposed COM's compliance with accreditation standards. Following the site visit, the COCA reviews the site visit report and other submitted information and grants pre-accreditation status to a proposed COM that meets the pre-accreditation standards. Once a proposed COM receives pre-accreditation status, it may begin to recruit, accept applications from, and admit prospective students. We note that prior to 2017, the COCA used the term ''provisional status'' instead of ''pre-accreditation status.''

The COCA may grant accreditation status to a COM that has achieved pre-accreditation status and meets the standards for accreditation. These accreditation statuses include accreditation with exceptional outcome, accreditation, accreditation with heightened monitoring, accreditation with warning, and accreditation with probation. Any accreditation status constitutes full accreditation, in contrast to pre-accreditation status or candidate status, which do not constitute full accreditation status.

The COCA defines a branch campus as a geographically separate location apart from the COM's main campus that is: Permanent in nature; offers courses in educational programming leading to a doctorate in osteopathic medicine; has its own faculty and administrative or supervisory organization; and maintains its own budgetary and hiring authority. A COM that establishes a branch location must apply for and receive separate approval from the COCA; the application process has four steps: A written application and branch campus self-study, a progress report, a revised branch campus self-study and site visit, and a final, pre-operational site visit.

The COCA defines an additional location as a location that is geographically separate from the main campus of a COM, but unlike a branch location, shares administration, faculty, curriculum, and budgetary authority with the main campus. Additional locations receive accreditation through the main campus of the COM following the review of documents and a survey site visit, after which a COM may enroll students in the additional location.

Based on information gathered from LCME and the COCA about new medical schools, additional locations and branch campuses, we are proposing that hospitals located in the following 35 states and one territory, referred to as Category Three states, are Category Three hospitals: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Mississippi, Missouri, Nevada, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Puerto Rico, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin. If a hospital is located in a State not listed here, but believes the State in which it is located should be on this list, the hospital may submit a formal comment on this proposed rule to make a change to this list, or must provide documentation with submission of its application to CMS that the State in which it is located has a medical school or additional location or branch campus of a medical school established on or after January 1, 2000. Pursuant to the statutory language, all hospitals in such states are eligible for consideration; the hospitals, themselves, do not need to meet the conditions of section 1886(h)(9)(B)(ii)(III)(aa) or (bb) of the Act in order to be considered.

(e) Determination of Hospitals That Serve Areas Designated as Health Professional Shortage Areas Under Section 332(a)(1)(A) of the Public Health Service Act (Category Four)

The fourth category specified in the law consists of hospitals that serve areas designated as health professional shortage areas under section 332(a)(1)(A) of the Public Health Service Act (PHSA), as determined by the Secretary. We refer to this category as Category Four.The Health Resources and Services Administration (HRSA) designates certain areas as health professional shortage areas (HPSAs). Section 332(a)(1)(A) of the Public Health Service Act (PHSA), states that a ''health professional shortage area'' is an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines lacks sufficient health care providers to meet the health care needs of that area's population. HRSA designates HPSAs for primary care, mental health, and dental health.

A geographic area may be designated as a HPSA under section 332(a)(1)(A) of the PHSA only on the basis of a shortage of services for the entire population within that area (a ''geographic HPSA''). Subsequent clauses of 332(a)(1) refer to other types of HPSAs, to which we will return later in this proposed rulemaking. The geographic area to which a geographic HPSA is assigned may be a single county, multiple counties, a county subdivision, or a census tract.

Section 126 of the CAA does not explicitly address the question of how HPSAs for different medical specialties should factor into determining which hospitals serve areas designated as HPSAs. In our consideration of this question, we began by examining the use of HPSAs in the HPSA Physician Bonus Program authorized under section 1833(m) of the Act. This program is relevant to our belief, because Congress established the program as an incentive to attract new

physicians to medically underserved communities and to encourage physicians in those areas to remain there (69 FR 47517 through 47518).

The HPSA Physician Bonus Program was created by Section 4043 of the Omnibus Budget Reconciliation Act (OBRA) of 1987, which added section 1833(m) to the Act. It provides incentive payments to physicians who furnish services to an individual in an area that is designated as a HPSA. Originally, under section 1833(m) of the Act, a 5 percent payment was added, beginning January 1, 1989, to the amounts otherwise payable to physicians who furnish services to Medicare patients in designated HPSAs. Section 6102 of OBRA 1989 further amended section 1833(m) of the Act to raise the amount of this incentive payment from 5 percent to 10 percent for services furnished after December 31, 1990. The OBRA 1989 amendment also expanded eligible service areas to include both rural and urban HPSAs.

We first examined the role of primary care geographic HPSAs in the HPSA Physician Bonus program. Physicians furnishing services in a primary care geographic HPSA are eligible to receive the bonus payments and the payments apply to all physicians who perform covered services within a primary care geographic HPSA, *regardless of specialty.* Similarly, section 126 of the CAA does not explicitly distinguish between physician specialties for purposes of allocating the additional residency positions. Therefore, we are proposing that primary care geographic HPSAs be considered in determining what hospitals qualify under Category Four and that hospitals that have main campuses or provider-based facilities in these HPSAs may apply for additional residency positions for any specialty. We also note CMS used primary care HPSAs for the allocation of residency positions for purposes of section 5503 of the ACA (75 FR 72147).

We next considered the use under the HPSA Physician Bonus Program of areas that are solely mental health geographic HPSAs and not also primary care geographic HPSAs. We will refer to these areas as mental health only geographic HPSAs. The HPSA Physician Bonus Program provides incentive payments for services provided in mental health only geographic HPSAs, *but only for services provided by psychiatry provider specialties.* The distinction between primary care geographic HPSAs, in which all physician provider specialties, including psychiatry provider specialties, receive the incentive payments, and mental health only geographic HPSAs, in which only psychiatry provider specialties receive the incentive payments, is relevant to the question of how mental health geographic HPSAs should factor into determining hospitals that serve areas designated as HPSAs for purposes of section 126 of the CAA. We believe that it is appropriate to incorporate this feature of the HPSA Physician Bonus Program as well, and propose to use mental health only geographic HPSAs for mental health providers accordingly in the determination of hospitals that serve areas designated as HPSAs. Thus, we are proposing that hospitals that only have main campuses or provided-based facilities in mental health only geographic HPSAs may only apply for residency positions for psychiatry residency programs.

We next considered dental geographic HPSAs. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of allopathic and osteopathic residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during the same cost reporting period is applied effective for discharges occurring on or after October 1, 1997. Given that dental residents are not included in this statutory cap and that section 126 of the CAA distributes additional residency positions in the context of the statutory cap, we are not proposing that dental geographic HPSAs factor into the determination of whether a hospital serves a HPSA for purposes of section 126.

In summary, we are proposing to consider geographic HPSAs for primary care and mental health providers for purposes of determining hospitals that serve areas designated as HPSAs. We are proposing that hospitals that only have campuses or provider-based facilities in mental health only geographic HPSAs may only apply for positions for psychiatry residency programs. We are not proposing to consider dental HPSAs as dental FTE residents are not subject to a hospital's IME and direct GME caps.

We next considered what hospitals serving areas designated as primary care or mental health HPSAs means for purposes of Category Four. As with the question regarding the role of primary care, mental health, and dental HPSAs, section 126 of the CAA does not explicitly address this question.

There are many possible interpretations of what hospitals that serve areas designated as primary care or mental health HPSAs means for purposes of Category Four. The most expansive interpretation might be that this refers to the universe of hospitals where each hospital provides care to at least one patient that resides in a HPSA without regard to the location of the main campus of the hospital or of its other patient care locations. This interpretation could be made less expansive by developing a relative or absolute threshold for the number of patients of the hospital that reside in HPSAs. It could also be made less expansive by considering whether the physical location of the main campus of the hospital and/or its other patient care locations are inside of or proximate to a HPSA.

In considering this issue, we prioritized objective factors that would maximize distribution of GME positions to residency programs serving underserved populations. See section V.J.2.a.4. for a further discussion of prioritizing care to underserved populations.) To this end, we propose that a hospital is qualified under Category Four if it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health geographic HPSA. Additionally, as part of the qualification requirements under Category Four, in the residency program for which the hospital is applying, at least 50 percent of the residents training time over the duration of the program must occur at those locations in the HPSA. We believe it is important to avoid the possibility that a hospital with provider-based facilities in multiple locations, some of which may not be located in a HPSA, uses an additional residency position mostly or entirely to serve populations that face no health service shortage.

A Category Four hospital must submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report that it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health geographic HPSA, and in the program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program occurs at those locations in the HPSA.

For example, Hospital A applies under Category Four for a psychiatry residency program. Its main campus is located in a non-HPSA area and it has one provider-based facility located in a mental health only geographic HPSA. Hospital A must attest that residents training in the psychiatry residency

program spend at least 50 percent of the duration of their training in the program at its provider-based facility located in the mental health only geographic HPSA. As another example, Hospital B applies for a residency program. Its main campus is located in a primary care geographic HPSA and it has two provider-based facilities, one in the same geographic HPSA as the main campus and one in a non-HPSA area. Hospital B must attest that residents training in the program will spend at least 50 percent of the duration of their training in the program on the main campus or at the provider-based facility located in the geographic HPSA, combined (for example, 30 percent of the time on the main campus and 20 percent at the provider-based facility).

(f) Determination of Qualifying Hospitals

Section 1886(h)(9)(F)(ii) defines a qualifying hospital as a hospital described in any of the subclauses (I) through (IV) of subparagraph (B)(ii). In other words, a qualifying hospital is a Category One, Category Two, Category Three, or Category Four hospital, or one that meets the definitions of more than one of these categories.

(3) Number of Residency Positions Made Available to Hospitals and Limitation on Individual Hospitals

(a) Number of Residency Positions Made Available to Hospitals

Section 1886(h)(9)(A)(ii)(II) limits the aggregate number of total residency positions made available in a single fiscal year across all hospitals to no more than 200. In order to provide these additional residency positions to hospitals as quickly as possible, we are proposing to make 200 residency positions available for FY 2023 and each subsequent year.

(b) Limitation on Individual Hospitals

We expect the demand from hospitals for the aggregate number of total residency positions made available for each fiscal year to significantly exceed the 200 maximum. For example, there are currently over 300 teaching hospitals that have their main campus located in a primary care or mental health HPSA. We expect the majority of these hospitals would apply for additional residency positions because they would qualify under our proposed Category Four. Even if we were to exclusively allocate the maximum 200 positions permitted under the statute each year to these hospitals, which are only a subset of Category Four hospitals and Category Four itself is only one of four categories, it would still be insufficient to award even 1.0 FTE to each hospital each year. Therefore, in order to make additional residency positions available to more hospitals each year, we are proposing to limit the increase in the number of residency positions made available to each individual hospital to no more than 1.0 FTE each year. We note that this is not 1.0 FTE for each program at a hospital each year, it is 1.0 FTE for each hospital each year.

As noted earlier, section 1886(h)(9)(C) places certain limitations on the distribution of the residency positions, one of which is that a hospital may not receive more than 25 additional FTE residency positions. Under our proposed 1.0 FTE limitation, no hospital would receive more than 25 additional FTE residency positions.

(4) Prioritization of Applications From Hospitals for Residency Programs That Serve Underserved Populations

(a) Use of Geographic HPSAs and Population HPSAs

The Executive Order on ''Ensuring an Equitable Pandemic Response and Recovery'' noted that the COVID–19 pandemic has exposed and exacerbated severe and pervasive health and social inequities in America (see *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/*.)

In order to help address these exposed health inequities longer term, we believe that it would be appropriate to prioritize the applications from hospitals that will use the additional residency positions under section 126 of the CAA in residency programs serving underserved populations.This prioritization is already partially reflected in our proposed Category Four, where we discussed maximizing the number of GME positions distributed to residency programs serving underserved populations in geographic HPSAs designated by HRSA under PHSA section 332(a)(1)(A). However, under PHSA section 332(a)(1)(B), HRSA also designates HPSAs on the basis of a shortage of services for a specific subset of the population (''population HPSAs'') rather than the entire population in an area as is the case in geographic HPSAs. These population subsets include, but are not limited to: Low-income populations, Medicaid-eligible population, Native American populations, homeless populations, and migrant farmworker populations. (For information on the location and types of population HPSAs see *https://data.hrsa.gov/tools/shortage-area/hpsa-find*).

In order to more fully address health inequities for underserved populations, we believe that it also would be appropriate to prioritize the applications from hospitals that serve the specific designated underserved population of a population HPSA.

We have already discussed our proposed definition in Category Four of hospitals that serve the populations of geographic HPSAs. Similar to that approach, we propose that a hospital serves a population HPSA if it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health population HPSA, and any such locations serve the designated underserved population of that HPSA. Additionally, as part of the qualification requirements under Category Four, in the residency program for which the hospital is applying, at least 50 percent of the residents' training time over the duration of the program must occur at those locations in the HPSA. As with geographic HPSAs, we believe it is important to avoid the possibility that a hospital with provider-based facilities in multiple locations, some of which may not be located in a population HPSA or serve the designated population of that HPSA, uses an additional residency position mostly or entirely to serve populations that face no health service shortage.

Also similar to our proposed use of geographic HPSAs, we are proposing that hospitals that only have main campuses or provider-based facilities in mental health only population HPSAs may only apply for position for a psychiatry residency programs.Under our proposal, a hospital must submit an attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report that it has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in a primary care or mental health population HPSA, any such locations serve the designated underserved population of that HPSA, and in the program for which the hospital is applying at least 50 percent of the residents' training time over the duration of the program occurs at those locations in the HPSA.

We recognize that our proposed approach for population-based HPSAs means that we potentially would be awarding a residency position for the provision of care that is not exclusively provided to the designated underserved population for which the shortage exists. However, in the context of our proposal discussed in this proposed rule

to use HPSA scores to prioritize applications by the severity of the shortages, our proposal to limit the number of additional residency positions awarded to 1.0 FTE per hospital each year, and our proposal that at least 50 percent of the training time over the duration of the program occur at locations in the HPSA that serve the designated underserved population of that HPSA, we believe it is sufficient for the residents in a program to provide care to the designated underserved population of that HPSA, and it is not necessary for residents to provide care exclusively to that population.

We note that HRSA also designates certain facilities as HPSAs, either through an application process or on the basis of regulation or statute, under PHSA section 223(a)(1)(C). The process for facility HPSA designation is dissimilar from that for geographic and population HPSAs. Further, a HPSA score for a facility does not reflect on the adequacy of the health care workforce outside that facility in a geographic area, and so it is not comparable to geographic or population HPSAs. Therefore, we are not proposing to use facility HPSA designations for the purposes of this rulemaking.

We also note that there are teaching hospitals that may not have facilities in areas designated as geographic or population HPSAs, but that under its Medicare provider agreement operate one or more facilities that serve areas for which there exists a shortage of providers. If this is the case, we recommend that a hospital interested in applying for FTE resident cap positions under this section contact its State or territorial Primary Care Office (PCO). HRSA maintains cooperative agreements with the 54 State and territorial PCOs, which conduct needs assessments and submit applications to HRSA to designate areas as HPSAs. We refer interested parties to 42 CFR part 5 and 57 FR 2473 for information on procedures for HPSA designation for primary care and mental health HPSAs, respectively.

In summary, we propose to prioritize applications from qualifying hospitals (that is, hospitals that qualify under categories One through Four, as previously described), for residency programs that serve underserved populations in geographic HPSAs or population HPSAs. In the next section we discuss our proposed use of HPSA scores for this purpose.

(b) Use of HPSA Scores for Prioritization

HRSA assigns HPSA scores on a scale of 0 to 25 as a measure of the severity of a primary care or mental health provider shortage in a geographic area, with higher scores indicating a more severe health professional shortage. Using HPSA scores to differentiate applications from hospitals that qualify under categories One through Four would allow us to optimize the use of the limited number of additional residency positions under section 126 of the CAA and best address health inequities by focusing those residency positions on underserved populations with the most need.

In preparing its application for an additional residency position for a program, hospitals should refer to HRSA's HPSA Find Tool (*https://data.hrsa.gov/tools/shortage-area/hpsa-find*) to obtain the HPSA score of the HPSA served by the program and include this score in its application. A HPSA is served by a program if that program meets the requirements discussed earlier. Given our proposal to limit the additional positions awarded to individual hospitals to 1.0 FTE for any given year, we are proposing that a hospital may not submit more than one application in any fiscal year. Given the limited number of residency positions available and the number of hospitals we expect to apply, we expect that a hospital would choose to apply for a program that serves the HPSA with the highest score among its programs, but a hospital is not required to do so.

We would allocate 1.0 FTE to each hospital with the highest HPSA score, prorating only in the event that the number of hospitals with the highest score exceeds the number of residency positions available. If the number of hospitals with the highest score is less than the number of residency positions available, each hospital with the next highest score would receive 1.0 FTE, with proration again occurring only in the event that the number of hospitals with this score exceeds the number of positions remaining. We would continue in this manner, moving on to hospitals with the next highest score until all available positions are distributed. We note that hospitals applying for residency positions for programs that do not serve HPSAs are not categorically excluded, but those applications would have the lowest priority.

As an illustrative example, assume the following hospitals apply, Hospitals A through HV. Assume there are 200 additional residency positions available. We propose that Hospitals A through ET would each get 1.0 FTE, while Hospitals EU through HV would each get a prorated FTE award of 0.625, as follows:

HOSPITAL NAME	HPSA SCORE	FTEs AWARDED	FTEs DISTRIBUTED/REMAINING
A-AX (50 hospitals)	25	1.0	50/150
AY-CV (50 hospitals)	24	1.0	50/100
CW-ET (50 hospitals)	21	1.0	50/50
EU-HV (80 hospitals)	19	.625	50/0

In summary, under our proposal, additional residency positions under section 126 of the CAA will be distributed to hospitals that qualify under categories One through Four based on the HPSA score of the HPSA served by the residency program for which each hospital is applying, with programs serving higher HPSA scores receiving higher prioritization. Hospitals applying for residency positions for programs that do not serve HPSAs are not categorically excluded, but those applications would have the lowest priority.

(5) Alternative Considered for Prioritization

As alterative to our proposed prioritization approach, we considered a simpler prioritization approach for FY 2023 that would allow additional time to work with stakeholders to develop a more refined approach for future years. Under this alternative approach, CMS

would distribute 200 additional residency positions for FY 2023 among hospitals that qualify in Category One, Category Two, Category Three, and/or Category Four, with higher priority given to applications from hospitals that qualify in more categories. Hospitals that qualify under all four categories would receive top priority, hospitals that qualify under any three of the four categories would receive the next highest priority, then any two of the four categories, and finally hospitals that qualify under only one category. We would distribute 1.0 FTE to each hospital that qualified under all four categories, prorating only in the event that the number of hospitals that qualified under all four categories exceeds 200. If the number of hospitals that qualified under all four categories is less than 200, each hospital that qualified under three out of four categories would receive 1.0 FTE, with proration again occurring only in the event that the number of hospitals that qualified under three out of four categories exceeds the number of positions remaining. We would continue in this manner, moving on to hospitals that qualified under two out of four and one out of four categories until all 200 positions are distributed.

We seek comment on this alternative prioritization approach considered to allow for additional time to work with stakeholders to develop a more refined approach for future years.

(6) Distributing At Least 10 Percent of Positions to Each of the Four Categories

Section 1886(h)(9)(B)(ii) of the Act requires the Secretary to distribute at least 10 percent of the aggregate number of total residency positions available to each of the following categories of hospitals discussed earlier: Category One, Category Two, Category Three, and Category Four.

We believe that because it is possible for a hospital to be eligible for distribution of additional residency positions via more than one of the four categories, Category One, Two, Three or Four, there is a strong likelihood that by prioritizing applications by HPSA score the result will be that 10 percent or more of the additional residency positions will be distributed to hospitals in each of the four categories. We propose to collect information regarding qualification for all four categories in applications to allow us to track progress in meeting all statutory requirements, and evaluate the need to modify the distribution methodology in future rulemaking.

(7) Hospital Attestation to National CLAS Standards

In order to ensure that the residents are educated and trained in culturally and linguistically appropriate policies and practices, we propose that all applicant hospitals would be required to attest that they meet the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards). By requiring attestation by hospitals that training programs meet CLAS standards, CMS would ensure the section 126 additional residency position allocation broadens the availability of quality care and services to all individuals, regardless of preferred language, cultures, and health beliefs. (For more information on the CLAS standards, please refer to *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53*).

(8) Payment for and Aggregation of Additional FTE Residency Positions Awarded Under Section 126 of the CAA

Section 1886(h)(9)(D) requires that CMS pay a hospital for additional positions awarded under this paragraph using the hospital's existing direct GME PRAs for primary care and OB/GYN programs and non-primary care programs consistent with the regulations at § 413.77. However, similar to our implementation of section 5503 in the CY 2011 OPPS final rule (75 FR 72192) with respect to the application of direct GME PRAs for primary care and nonprimary care residents, for the implementation of section 126 of the CAA, we are proposing that a hospital that receives additional positions under section 126 would be paid for FTE residents counted under those positions using the same primary care and nonprimary PRAs for which payment is made for FTE residents subject to the 1996 FTE cap. We are expecting to revise Worksheet E–4 to add a line on which hospitals would report the number of FTEs by which the hospital's FTE caps were increased for direct GME positions received under section 126.

(9) Conforming Regulation Amendments for 42 CFR 412.105 and 42 CFR 413.79

Section 126 of the CAA, under clause (b), amends section 1886(d)(5)(B) of the Act to provide for increases in FTE resident positions for IME payment purposes as well. Specifically, a new section 1886(d)(5)(B)(xii) is added to state that for discharges occurring on or after July 1, 2023, if additional payment is made for FTE resident positions distributed to a hospital for direct GME purposes under section 1886(h)(9), the hospital will receive appropriate IME payment based on the additional residency positions awarded using the same IME adjustment factor used for the hospital's other FTE residents. We are proposing conforming amendments to the IME regulations at 42 CFR 412.105 to specify that effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in 42 CFR 413.79(p) are met.

We are also proposing to amend our regulations at 42 CFR 413.79 to codify our proposal to specify that—(1) for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS; and (2) FTE resident cap positions added under section 126 of Public Law 116–260 may be used in a Medicare GME affiliation agreement beginning in the 5th year after the effective date of those FTE resident cap positions.

(10) Prohibition on Administrative and Judicial Review

Section 126 of the CAA, under clause (c), prohibits review of section 1886(h)(9) of the Act. Specifically, it amends section 1886(h)(7)(E) of the Act by inserting ''paragraph (9),'' after ''paragraph (8),''. Therefore, we are proposing that the determinations and distribution of residency positions under sections section 1886(d)(5)(B)(xii) and 1886(h)(9) of the Act are final without administrative or judicial review.

(11) Report by the Comptroller General

We note here for reference that section 126(d) of the CAA requires the Comptroller General of the United States to conduct a study and submit to Congress two reports on section 126 of the CAA, after the 5-year period of implementation is complete.

(12) Application Process for Receiving Increases in FTE Resident Caps

In order for hospitals to be considered for increases in their FTE resident caps, each qualifying hospital must submit a timely application. We are proposing that an application be considered timely for additional residency positions effective July 1 of fiscal year if it is completely submitted by January 31 of

the prior fiscal year. The following information must be submitted on an application to be considered completely submitted:

- The name and Medicare provider number of the hospital.
- The name of the Medicare contractor to which the hospital submits its Medicare cost report.
- The residency program for which the hospital is applying to receive an additional position.
- FTE resident counts for direct GME and IME and FTE resident caps for direct GME and IME reported by the hospital in the most recent as-filed cost report. (Including copies of Worksheets E, Part A, and E–4).
- If the hospital qualifies under Demonstrated Likelihood Criterion 1 (New Residency Program), which of the following applies:

☐ Application for approval of the new residency program has been submitted to the ACGME or the American Board of Medical Specialties (ABMS) by the application deadline for that year.

☐ The hospital has submitted an institutional review document or program information form concerning the new residency program in an application for approval of the new program by the application deadline for that year.

☐ The hospital has received written correspondence by the application deadline for that year from the ACGME or ABMS acknowledging receipt of the application for the new residency program, or other types of communication from the accrediting bodies concerning the new program approval process (such as notification of site visit).

- If the hospital qualifies under Demonstrated Likelihood Criterion 2 (Expansion of an Existing Residency Program), which of the following applies:

☐ The hospital has approval by the application deadline from an appropriate accrediting body (the ACGME or ABMS) to expand the number of FTE residents in the program.

☐ The hospital has submitted by the application deadline an institutional review document or program information form for the expansion of the existing residency training program.

- Identification of the category that describes the hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act):

☐ (I) The hospital is located in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act) or are treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Social Security Act.

☐ (II) The reference resident level of the hospital (as specified in section 1886(h)(9)(F)(iii) of the Social Security Act) is greater than the otherwise applicable resident limit.

☐ (III) The hospital is located in a State with a new medical school (as specified in section 1886(h)(9)(B)(ii)(III)(aa) of the Act), or with additional locations and branch campuses established by medical schools (as specified in section 1886(h)(9)(B)(ii)(III)(bb) of the Act) on or after January 1, 2000.

☐ (IV) The hospital serves areas designated as health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service Act, as determined by the Secretary.

- The HPSA (if any) served by the residency program for which the hospital is applying and the HPSA score for that HPSA.
- An attestation, signed and dated by an officer or administrator of the hospital who signs the hospital's Medicare cost report, of the following:

''I hereby certify that the hospital is a Qualifying Hospital under section 126 of Division CC of the Consolidated Appropriations Act, 2021 (per section 1886(h)(9)(F)(ii) of the Social Security Act).

''I hereby certify the demonstrated likelihood that the hospital will fill the position made available under section 126 of Division CC of the Consolidated Appropriations Act, 2021 within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary (per section 1886(h)(9)(B)(i) of the Social Security Act).

''I hereby certify that the hospital agrees to increase the number of its residency positions by the amount the hospital's FTE resident caps are increased under section 126 of Division CC of the Consolidated Appropriations Act, 2021, if awarded positions (per section 1886(h)(9)(C)(ii) of the Social Security Act).

''I hereby certify that if the residency program for which the hospital is applying serves a geographic or population Health Professional Shortage Area (HPSA), that the hospital has its main campus or a provider-based facility (under 42 CFR 413.65) physically located in that HPSA, any such locations serve the designated underserved population of that HPSA in the case of a population HPSA, and in the residency program for which the hospital is applying, at least 50 percent of the residents training time over the duration of the program occurs at those locations in the HPSA.

''I hereby certify that the hospital meets the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards).

''I hereby certify that I understand that misrepresentation or falsification of any information contained in this application may be punishable by criminal, civil, and administrative action, fine and/or imprisonment under Federal law. Furthermore, I understand that if services identified in this application were provided or procured through payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil, and administrative action, fines and/or imprisonment may result. I also certify that, to the best of my knowledge and belief, it is a true, correct, and complete application prepared from the books and records of the hospital in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding Medicare payment to hospitals for the training of interns and residents.''

The completed application must be submitted to CMS using an online application system under development. A link to the online application system as well as instructions for accessing the system and completing the online application process will be made available on the CMS DGME website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME* when the FY 2022 IPPS/LTCH PPS final rule goes on display.

We note that the burden associated with this information collection requirement is the time and effort necessary to review instructions and register for the electronic submission system as well as the time and effort to gather, develop and submit various documents associated with a formal request of resident slot increases from teaching hospitals to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA); and as discussed in section XII.B.5., the burden associated with these requests will be discussed in a forthcoming information collection request, which is currently under development.

We are soliciting comments on our proposals to implement section 126 of the CAA to help address health inequities and prioritize applications from hospitals that will use the additional positions in residency programs serving underserved populations.

b. Proposal for Implementation of Section 127 of the CAA, ''Promoting Rural Hospital GME Funding Opportunity''

To encourage the training of residents in rural areas, section 407(c) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113) (BBRA) amended section 1886(h)(4)(H) of the Act to add a provision (subsection (iv)) stating that, in the case of a hospital that is not located in a rural area (an urban hospital) that establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area, or has an accredited training program with an integrated rural track, the Secretary shall adjust the urban hospital's cap on the number of FTE residents under subsection (F), in an appropriate manner in order to encourage training of physicians in rural areas. Section 407(c) of Public Law 106–113 was effective for direct GME payments to hospitals for cost reporting periods beginning on or after April 1, 2000, and for IME payments applicable to discharges occurring on or after April 1, 2000. We refer readers to the August 1, 2000 interim final rule with comment period (65 FR 47026, 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39828, 39902 through 39909) where we implemented section 407(c) of Public Law 106–113. The regulations for establishing rural track FTE limitations are located at 42 CFR 413.79(k) for direct GME and at 42 CFR 412.105(f)(1)(x) for IME.

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57027), we finalized a revision to the regulations at § 413.79(k) (and which, in turn, affect IME adjustments under § 412.105(f)(1)(x)) to permit that, in the first 5 program years (rather than the first 3 program years) of the rural track's existence, the rural track FTE limitation for each urban hospital would be the actual number of FTE residents training in the rural training track at the urban hospital, and beginning with the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural training track's existence, the rural track FTE limitation would take effect. However, as previously stated, due to the statutory language at sections 1886(d)(5)(B) and 1886(h)(4)(H)(iv) of the Act as implemented in our regulations at §§ 412.105(f)(1)(v)(F) and 413.79(d)(7), except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, FTE residents in a rural training track (RTT) program at the urban hospital are subject immediately to the 3-year rolling average for direct GME and IME. In addition, under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time).

Since implementation of the rural training track provision from the BBRA of 1999, stakeholders and advocates of residency training in rural areas have raised concerns about inequities and unintended consequences of the BBRA provision. First, the BBRA provision allows an urban hospital to receive additional cap slots based on the time that residents in the RTT train at the urban hospital. However, the provision does not specify that the Secretary provide a cap adjustment for rural hospitals participating in RTTs. As a result, unless the RTT program was new, the rural hospital could not receive FTE resident cap increases, resulting in direct GME and IME payments going only to the urban hospital for the urban portion of the training, with no attending funding going to the rural hospital for the rural portion of the training. Second, the statutory provision does not specify that the Secretary may provide a cap adjustment to urban hospitals or rural hospitals when an urban hospital adds additional rural locations to already existing RTTs. Third, the provision stated that the Secretary would adjust the caps of an urban hospital that establishes *separately accredited* approved medical residency training programs (or rural tracks) in a rural area. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine programs in the ''1–2 format'' (meaning, residents in the 1–2 format receive their first year experience at a core family medicine program in an urban area, and their second and third year experiences at another site, which may or may not be rural). Because the ACGME has only accredited family medicine programs in the 1–2 format, CMS interpreted the provision to mean that hospitals cannot seek funding opportunities for rural tracks developed in specialties other than family medicine. Fourth, residents added to a RTT were previously not exempt from the 3-year rolling average for IME and direct GME. We believe that section 127 of the CAA remedies each of these concerns, explained in more detail in this proposed rule.

(i) Cap Adjustment for Urban and Rural Hospitals Participating in Rural Training Track Programs

As amended by the BBRA, section 1886(h)(4)(H)(iv) of the Act provided for IME and direct GME FTE resident cap adjustments for an urban hospital that establishes separately accredited rural tracks; however, the statute did not provide for a similar adjustment to rural hospitals participating in rural tracks. Specifically, section 1886(h)(4)(H)(iv) refers to the case of a *hospital that is not located in a rural area* but establishes separately accredited approved medical residency training programs (or rural tracks) in a rural area. Because of this explicit incentive and permission for FTE resident cap adjustments for an urban hospital that establishes a rural track, the rural track does not need to be new for Medicare payment purposes, as it otherwise would in order for the urban hospital to qualify for the FTE resident cap adjustments. That is, under section 1886(h)(4)(H)(iv) of the Act, if an urban hospital already had an accredited family medicine residency program, it could establish from that existing family medicine program, for the first time, a rural track, and, assuming all applicable requirements are met, that urban hospital could receive IME and direct GME FTE resident cap adjustments. However, with regard to a rural hospital participating in the second and third years of training in the rural track, since the BBRA language did not mention cap adjustments to rural hospitals, only if the program is new for Medicare

payment purposes can the rural teaching hospital also receive a FTE resident cap adjustment for the program. (Under § 413.79(e)(3), any time that a rural hospital participates in training residents in a new program, the rural hospital may receive an increase to its FTE resident caps. We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917)). In this case, a rural track established from an already existing urban family medicine program would not meet the newness requirement for the rural hospital. Consequently, Division CC, section 127 of the CAA 2021 revised section 1886(h)(4)(H)(iv) of the Act to state that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, the Secretary must adjust in an appropriate manner the limitation under subparagraph (F) for such hospital *and each such hospital located in a rural area* that participates in such a training. This revision provides for cap adjustments for both the urban teaching hospital and the rural teaching hospital(s). We are proposing that each time an urban hospital and rural hospital establish a RTT program for the first time, even if the RTT program does not meet the newness criteria for Medicare payment purposes, both the urban and rural hospitals may receive a rural track FTE limitation. For example, Urban Hospital A has an existing internal medicine program. In July 2023, it partners with Rural Hospital 1 to create a RTT from the existing internal medicine program. We are proposing that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their resident caps (rural track FTE limitations) to reflect their portions of FTE residents training in the RTT. We propose to make various changes throughout the regulations text at 42 CFR 413.79(k) ''Residents training in rural track programs'' to accommodate the rural track FTE limitations for both urban and rural hospitals. We also provide examples in this proposed rule, regarding how the rural track FTE limitations are calculated, according to the same methodology already in place at 42 CFR 413.79(k)(1) and as previously explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57028).

(ii) Cap Adjustments When the Urban Hospital Adds Additional Rural Training Tracks

As previously stated, under section 1886(h)(4)(H)(iv) *prior* to enactment of the CAA, if an urban hospital already had an accredited family medicine residency program, it could, for the first time, establish a rural track from that existing family medicine program and, assuming all applicable requirements were met, such hospital could receive the IME and direct GME FTE resident cap adjustments. Because section 1886(h)(4)(H)(iv) gave this explicit permission for FTE resident cap adjustments to an urban hospital that establishes a rural track, the rural track program does not need to be new for Medicare payment purposes in order for the urban hospital to qualify for the FTE resident cap adjustments. (We refer readers to the FY 2010 IPPS/LTCH PPS final rule for the criteria identifying a new program for Medicare payment purposes (74 FR 43908 through 43917)). However, after establishing its first RTT, the urban hospital can receive a rural track limitation adjustment for additional established RTTs only if those additional programs are ''new'' for Medicare payment purposes. We believe that section 127 of the CAA amends section 1886(h)(4)(H)(iv) such that it permits us to adjust the resident caps of an urban hospital wishing to create additional RTTs *after establishing its first RTT,* while also adjusting the residents caps of the rural hospital(s) added by creating the subsequent RTTs. Section 127 of the CAA amends section1886(h)(4)(H)(iv) of the Act to add a new subclause which states that for cost reporting periods beginning on or after October 1, 2022, in the case of a hospital not located in a rural area that *established or establishes* a medical residency training program (or rural tracks) in a rural area . . . adjust in an appropriate manner the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training. Because the law now states ''established or establishes,'' *both past tense and future tense,* we believe the statute grants the Secretary unique authority not previously held; that is, the authority to *prospectively* allow (under certain circumstances) cap adjustments to *existing RTTs expanded in a cost reporting period beginning on or after October 1, 2022.* That is, the provision gives explicit permission to adjust the RTT limitations of an urban hospital wishing to create additional RTTs *after establishing its first RTT,* while also adjusting the residents caps of the additional rural hospital(s) added by creating the second (or third, etc.) RTT. We believe this new statutory authority is separate and distinct from the statute's requirement that, for IME and direct GME payment purposes, caps can be adjusted only for new teaching urban hospitals and for rural hospitals with new programs under section 1886(h)(4)(H)(i) of the Act. That is, in general, urban hospitals becoming teaching hospitals for the first time and rural hospitals may receive cap adjustments only if the program(s) in which they train residents is ''new'' in accordance with Medicare rules (as explained in detail at 74 FR 43908 through 43917). Therefore, under the explicit authority under section 127 of the CAA, we are proposing to prospectively allow increases to the IME and direct GME caps of both the participating urban and rural hospitals that *expand a qualifying RTT.* We are proposing that if, in a cost reporting period beginning on or after October 1, 2022, an urban hospital with an existing RTT (''hub'') adds an additional RTT (''spoke'') to the existing urban core program of the same specialty, the urban and rural hospitals may receive adjustments to their rural track FTE limitation. (For ease of reference, we are referring to the urban core hospital as the ''hub'' and the one or more RTTs as the ''spokes'' associated with that urban ''hub.'') For example, Urban Hospital A has an existing family medicine program. In 2015, Urban Hospital A partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and received rural track FTE limitation to reflect the time that residents training in the RTT spent at its facility. In July 2023, Urban Hospital A partners with Rural Hospital 2 in a different rural area of the State, to create an additional family medicine RTT (adding another ''spoke'' to the existing urban program ''hub.'') We are proposing that both Urban Hospital A and Rural Hospital 2 may receive adjustments to their resident caps (rural track FTE limitations) to reflect the portion of the time that FTE residents in the second family medicine RTT ''spoke'' spend at their respective facility. We believe that allowing prospective adjustments to RTT FTE limitations for additional RTT ''spokes'' added in cost reporting periods beginning on or after October 1, 2022 is an efficient means of addressing rural healthcare workforce shortages, by allowing already experienced and successful urban ''hub'' RTTs to branch out and partner with additional rural communities, rather than relying solely on starting RTTs from scratch. That is, with the ability for CMS to provide funding for additional spokes, it should be easier for urban hospitals that already have one RTT to reach rural areas more quickly and efficiently with the addition

of more spokes, rather than starting brand new ''hubs''. However, we are proposing to limit the increases to the urban and rural hospitals' RTT FTE limitations only in the instance where additional residents are recruited to add a *new rural ''spoke'' RTT,* and *not* to allow increases to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT ''spoke.'' We believe it is appropriate to do so because section 127 of the CAA states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, the Secretary shall *consistent with the principles of subparagraphs (F)* and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program and, in accordance with such rules, *adjust in an appropriate manner* the limitation under subparagraph (F) for such hospital and each such hospital located in a rural area that participates in such a training. That is, the statute directs the Secretary to adjust the cap (the limitation under subparagraph (F)) in an appropriate manner. We believe that ''appropriate'' means not rendering the RTT FTE limitations meaningless. If we would allow adjustments to the RTT FTE limitations at any time, for any type or any amount of expansion even to already existing rural site ''spokes,'' there would, in essence, not be any RTT FTE limitation at all. As a matter of public policy, as long as the FTE resident caps (that is, the ''limitation under subparagraph (F)'') are in place, we believe that CMS should be judicious with providing for additional funded cap slots, as that, in turn, encourages thoughtful residency program expansion among hospital stakeholders. Therefore, we are proposing to limit the provision of an increase to the urban and rural hospitals' RTT FTE limitations only to the instance where additional residents are recruited to add a new rural RTT ''spoke'' to the existing urban ''hub'', and *not* to allow increases under this section to the RTT FTE limitations in the instance where the urban and rural hospital add additional FTE residents to an existing rural RTT ''spoke.'' As with the general FTE resident caps, since the slots associated with the RTT FTE limitation are fungible, urban and rural hospitals with multiple RTT ''spokes'' may reduce the number of FTE residents training at one track and ''spoke'' in order to accommodate an increase in training and funding at another track and ''spoke.'' For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program. Urban Hospital A received a cap/rural track FTE limitation to reflect residents in the RTT training at its facility. In July 2023, Urban Hospital A receives permission from the ACGME to permanently expand this family medicine RTT by 2 FTE residents, to train at both Urban Hospital A and Rural Hospital 1. We are proposing NOT to allow an adjustment to the rural track FTE limitation of Urban Hospital A and Rural Hospital 1 for the addition of 2 FTE residents, because this would be an expansion of an already existing RTT ''spoke.''

We also note that if the urban hospital already has an existing RTT in one specialty and an associated rural track FTE limitation, the urban hospital may also receive an adjustment to its rural track FTE limitation if it starts another RTT in a different specialty, because starting a RTT in a different specialty would not be an expansion of the already existing RTT. For example, Urban Hospital A has an existing family medicine program. In 2015, it partnered with Rural Hospital 1 to create a RTT from the existing family medicine program and, as a result, received a cap/rural track FTE limitation adjustment to reflect residents in the RTT training in its facility. In July 2023, Urban Hospital A partners once again with Rural Hospital 1 to create a RTT in internal medicine. We are proposing that both Urban Hospital A and Rural Hospital 1 may receive adjustments to their cap/rural track FTE limitations to reflect the time that residents train in the internal medicine RTT ''spoke'' in their respective facilities. Thus, Urban Hospital A and Rural Hospital 1 would have cap/rural track FTE limitations reflecting FTE residents training in both a family medicine RTT and an internal medicine RTT.

(iii) Removal of Requirement That Rural Track Must Be ''Separately Accredited''

Previously, section 1886(h)(4)(H)(iv) stated that the Secretary would adjust the caps of an urban hospital that establishes *separately accredited* approved medical residency training programs (or rural tracks) in a rural area. Historically, the ACGME has separately accredited family medicine programs in the ''1–2 format'' (meaning, residents in the 1–2 format receive their first year experience at a core family medicine program, and their second and third year experiences at another site, which may or may not be rural). Because the ACGME has only accredited family medicine programs in the 1–2 format, hospitals have not been able to seek additional funding opportunities for rural tracks developed in specialties other than family medicine. Since implementation of the original BBRA provision, stakeholders have expressed concern that FTE cap adjustments have not been permitted for sending residents to rural areas if the program was not a separately accredited family medicine RTT. Section 127 of the CAA removes the requirement that the rural track be ''separately accredited.'' Specifically, section 1886(h)(4)(H)(iv)(II) now states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area, or establishes an accredited program where more than 50 percent of the training takes place in a rural area, the Secretary may adjust the resident cap in an appropriate manner. (Residency programs, whether they are ''rural tracks'' or any other program, must still be accredited under the law in order to receive IME and direct GME payments; see section 1886(h)(4)(H)(iv)(II) of the Act). Therefore, we are proposing that effective for cost reporting periods beginning on or after October 1, 2022, so long as the program in its entirety is accredited by the ACGME, regardless of the specialty, it may qualify as a RTT and urban and/or rural hospitals receive rural track FTE limitations, assuming all other requirements are met.

(iv) Requirement That Greater Than 50 Percent of the Program Occurs in a Rural Area

Under existing regulations at 42 CFR 413.79(k)(1) and (2), the urban hospital establishing the RTT may only receive a cap/rural track FTE limitation to count residents in the RTT if the urban hospital rotates residents to either a rural hospital or rural non-provider site, for more than 50 percent of the duration of the program. As described in detail in rules implementing the original BBRA provision (see the August 1, 2000 interim final rule with comment period (65 FR 47033 through 47037) and the FY 2002 IPPS final rule (66 FR 39902 through 39909) where we implemented section 407(c) of Pub. L. 106–113), we adopted this greater than one-half duration rule based on the fact that residents training in separately accredited 1–2 family medicine RTTs spend greater than 50 percent of their training time in rural areas. We also wanted to ensure that cap adjustments would not be allowed for minimal

rotations to rural areas Section 1886(h)(4)(H)(iv)(II) is amended by section 127 of the CAA which states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or *establishes an accredited program where greater than 50 percent of the program occurs in a rural area,* the Secretary shall consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program. We believe section 127 of the CAA now requires in statute what CMS has required in regulation; that is, we are proposing that in order for urban or rural hospitals to receive FTE cap adjustments for residents training in RTTs, the residents must be in ''an accredited program where greater than 50 percent of the program occurs in a rural area.'' We believe that a ''medical residency training program (or rural tracks)'' refers to what the ACGME currently separately accredits as a 1–2 program; family medicine residencies that typically would have a first year in an urban hospital and second and third years in a rural hospital/setting. These separately accredited 1–2 family medicine RTTs may continue to maintain their RTT FTE limitations, assuming all applicable requirements are met. However, we are proposing that an ''accredited program where greater than 50 percent of the program occurs in a rural area'' is the new statutory authorization for development of rural tracks in specialties *other than* family medicine, because eligibility for cap adjustments is no longer tied exclusively to ''separately accredited'', 1–2 programs. Specifically, as long as a program in its entirety is accredited by the ACGME, whether the program is in family medicine or in another specialty, and the residents spend more than 50 percent of the entire program in a rural area, then prospectively for cost reporting periods beginning on or after October 1, 2022, we are proposing to also provide additional slots to any program in any specialty. Therefore, for all accredited specialties, we are proposing to require that an urban hospital may include in its FTE count, not to exceed its rural track FTE limitation, residents training in the urban hospital that are designated to rotate to a rural area for greater than 50 percent of the duration of the particular program. In addition, we are proposing that a rural hospital that is partnered with the urban hospital in the RTT would similarly include in its FTE count, not to exceed its rural track FTE limitation, the time residents train in the rural hospital only if the residents rotate to a rural area for greater than 50 percent of the duration of the particular program. For example, greater than 50 percent of the duration of a 3-year family medicine program would be more than 18 months rotating to a rural area; greater than 50 percent of the duration of a 4-year psychiatry program would be more than 24 months training in a rural area.

(v) Exemption From the 3-Year Rolling Average During the 5-Year Rural Track FTE Limitation Window

In the August 1, 2003 IPPS final rule (68 FR 45456 through 45457), we clarified our existing policy that although the rural track provision allows an increase to the urban hospital's FTE cap, sections 1886(h)(4)(H)(iv) and 1886(d)(5)(B) of the Act do not provide for an exclusion from the rolling average for the urban hospital for those FTE residents training in a rural track. These provisions are interpreted to mean that, except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, when an urban hospital with an FTE resident cap establishes a new rural track program or expands an existing rural track program, FTE residents in the rural track that are counted by the urban hospital are included in the hospital's rolling average calculation immediately. This policy is reflected in the regulation at § 412.105(f)(1)(v)(F) for IME and § 413.79(d)(7) for direct GME, and applies for IME and direct GME to cost reporting periods beginning on or after April 1, 2000.

In addition, as stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57028), under the regulations at § 412.105(a)(1)(i), no exception to the IME intern- and resident-to-bed (IRB) ratio cap is provided for residents in a rural track training program (except for new rural track programs begun by urban teaching hospitals that are establishing an FTE cap for the first time, or for rural hospitals, if the rural track meets the definition of a new program).

We believe that section 127 of the CAA amends section 1886(h)(4)(H)(iv) of the Act to provide for an exemption from the 3-year rolling average of the urban hospital and rural hospital during the 5-year growth window for FTE residents participating in rural tracks. Specifically, section 1886(h)(4)(H)(iv)(II) of the Act states that in the case of a hospital not located in a rural area that established or establishes a medical residency training program (or rural tracks) in a rural area or establishes an accredited program where greater than 50 percent of the program occurs in a rural area, *the Secretary shall consistent with the principles of subparagraphs* (F) and *(G)* and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs with respect to such a program. Subparagraph (F) is the FTE resident cap, and subparagraph (G) refers to the 3-year rolling average. This italicized language is the same as that used at section 1886(h)(4)(H)(i) regarding providing exemptions from the FTE resident cap and 3-year rolling average for new teaching hospitals starting new residency programs. That is, section 1886(h)(4)(H)(i) states: ''(i) New facilities.—The Secretary shall, *consistent with the principles of subparagraphs (F) and (G)* and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995.'' The previous rural track language at section 1886(h)(4)(H)(iv) did not mention subparagraph (G); therefore, the law did not exempt from the rolling average any residents participating in a rural track, even during the cap building window as we explained in the August 1, 2003 IPPS final rule (68 FR 45456 through 45457). Because section 127 of the CAA amends section 1886(h)(4)(H)(iv) to add in new subclause (II) which contains language modeled on the language for providing for FTE resident cap and rolling average exemptions in the case of new programs started on or after January 1, 1995, we are proposing that similarly, during the 5-year cap growth window for RTTs, the FTE residents participating in the RTT either at the urban hospital or a rural hospital would not be included in a hospital's 3-year rolling average calculation during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track. That is, just as residents in new programs are exempt from the 3-year rolling average until the cost reporting period that coincides with or follows the start of the sixth program year, similarly, effective for RTTs started in cost reporting periods beginning on or after October 1, 2022, for each rural track started, full-time equivalent residents at an urban hospital or rural hospital in a rural track program are excluded from the rolling average calculation during the cost reporting periods prior to the beginning

of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(vi) Proposed Changes to the Regulations Text

Although section 127 of the CAA directly amends section 1886(h) for direct GME, and does not specifically refer to amendments for IME, the existing language at section 1886(d)(5)(B)(viii) of the Act states that rules similar to the rules of subsection (h)(4)(H) shall apply for purposes of clauses (v) and (vi). Accordingly, the statutory authority to make corresponding changes to IME for rural tracks already exists. Clause (v) refers to the IME resident caps, and clause (vi) refers to the 3-year rolling average. Therefore, we are proposing to apply to the IME payment the new authority under section 1886(h)(4)(H)(iv) of the Act to allow both urban and rural hospitals to receive IME rural track FTE limitations, as well as an exemption from the IME 3-year rolling average for FTE residents during the 5-year cap building window. We are proposing to make appropriate changes to the regulations text for IME at 42 CFR 412.105(f)(1)(v)(F) and 412.105(f)(1)(x) to mirror the following proposed regulations text changes for direct GME:

- We propose to modify the definition of Rural Track FTE limitation at 42 CFR 413.75(b) to add ''or rural hospital''.
- We propose to remove the requirement at 42 CFR 413.79(d)(7) that FTE residents in the rural track are included in the 3-year rolling average during the 5-year cap building window.
- We propose to make various changes throughout the regulations text at 42 CFR 413.79(k) ''*Residents training in rural track programs.*''

(vii) Documentation Required for Medicare Administrative Contractor (MAC) to Pay for RTTs

We intend to amend or clarify as necessary the Medicare cost report, CMS–2552–10, Worksheets E, Part A for IME and E–4 for direct GME, to accommodate additional rural track limitations. We expect that with this new authority to pay for more RTTs, MACs will face an influx of payment requests. While, as with payment for any GME program, hospitals must submit necessary documentation, to make review and processing of these new RTT payment requests more manageable, we are reiterating the documentation requirements here. That is, in order to facilitate the implementation of increases to RTT FTE limitations, either via interim payments or cost report adjustments, an urban hospital ''hub'' that adds one or more rural ''spokes'' in one or more specialties, we propose that the urban and rural hospitals must show its MAC the following:

- The accreditation for the ''spoke'', information whether the ''spoke'' is in the same specialty as a RTT that the urban hospital already has, or whether the ''spoke'' is a newly created RTT in a different specialty.
- Intern and resident rotation schedules (or similar documentation) showing that residents in each particular RTT program (both hub and spokes overall) spend greater than 50 percent of their training in the program in a geographically rural area in order to receive IME and direct GME rural track FTE limitations.
- The number of FTE residents and the amount of time training in all 5 program years at both the urban and rural settings since establishment of the particular ''spoke'', so that the MAC may be able to verify the RTT cap limitation.

Following are examples of how the urban and rural hospital's rural track FTE limitations would be calculated:

Example 1: Urban Hospital and Rural Hospital jointly sponsor an accredited rural track program. The program is in internal medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area. Therefore, the Urban Hospital qualifies to receive a cap/rural track FTE limitation adjustment. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital
PGY2 0	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
PGY3 0	PGY3 0	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0
				5 Year Total = 24

Urban Hospital's 5 YEAR FTE TOTAL = 11.1
Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 12.9
5 Year FTE Total = 24

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0
PGY 2s = 2.0
PGY 3s = 2.0

Step 2: 2.0 × 3 (minimum accredited length) = 6.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [11.1/(24)] = 2.76.

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [12.9/(24)] = 3.24.

2.76 + 3.24 = 6.0, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's rural track FTE limitation is 3.24. (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the Urban Hospital and Rural Hospital exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

Example 2: Urban Hospital and Rural Hospital jointly sponsor an accredited rural track program. The program is in psychiatry (4 years minimum accredited length), and is accredited for a total of 8 residents, 2 in each program year (PGY). The residents spend PGY1 at Urban Hospital, and then the PGY2s and PGY3s and PGY4s rotate to a rural area, to train at both Rural Hospital and Rural Clinic (a nonprovider site). The PGY2 and PGY3 and PGY4 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent (that is, more than 24 months) of the duration of the 4 year program in the rural area. Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Rural Clinic. The rotations and the cap calculation are as follows:

YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital
PGY2 0	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
PGY3 0	PGY3 0	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)
PGY4 0	PGY4 0	PGY4 0	PGY4 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY4 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 8.0	TOTAL 8.0
				5 Year Total = 28

Urban Hospital's 5 YEAR FTE TOTAL = 11.5

Rural Hospital's 5 YEAR FTE TOTAL (includes time at Rural Clinic) = 16.5

5 Year FTE Total = 28

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0

PGY 2s = 2.0

PGY 3s = 2.0

PGY4s = 2.0.

Step 2: 2.0 × 4 (minimum accredited length) = 8.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: 8 × [11.5/(28)] = 3.29.

Step 4: Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: 8 × [16.5/(28)] = 4.71..

3.29 + 4.71 = 8.0, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 3.29. Rural Hospital's FTE cap adjustment is 4.71. (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the Urban Hospital and Rural Hospital exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

Example 3: Refer to Example 1 (as previously described), where Urban Hospital and Rural Hospital jointly sponsor an accredited internal medicine rural track program. The program is in internal medicine (3 years minimum accredited length), and is accredited for a total of 6 residents, 2 in each program year (PGY). Urban Hospital's rural track FTE limitation is 2.76. Rural Hospital's FTE cap adjustment is 3.24. In July 2023, Urban Hospital partners with Second Rural Hospital in a different rural part of the State to sponsor another internal medicine RTT (that is, Urban Hospital internal medicine ''hub'' is adding another ''internal medicine RTT ''spoke''.) Urban Hospital adds 2 FTE residents to train in PGY1 at the Urban Hospital, and then the PGY2s and PGY3s rotate to a rural area, to train at both Second Rural Hospital and Second Rural Clinic (a nonprovider site). The PGY2 and PGY3 residents, while mostly assigned to the rural area, do come back to the Urban Hospital for some required training. However, the residents spend more than 50 percent of the duration of the 3 year program in the rural area. Therefore, Urban Hospital qualifies to receive another rural track FTE limitation. Second Rural Hospital incurs the cost of the salaries and fringe benefits of the residents for the time spent training at Second Rural Clinic and meets other applicable requirements at § 413.78(g) to be able to count the time residents spend training at the Second Rural Clinic. The rotations and the cap calculation are as follows:

YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital	PGY1 2.0 Urban Hospital
PGY2 0	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)	PGY2 2 @ .90 Rural Hospital and Rural Clinic (1.8), 2 @ .10 Urban Hospital (.20)
PGY3 0	PGY3 0	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)	PGY3 2 @ .95 Rural Hospital and Rural Clinic (1.9), 2 @ .05 Urban Hospital (.10)
TOTAL 2.0	TOTAL 4.0	TOTAL 6.0	TOTAL 6.0	TOTAL 6.0
				5 Year Total = 24

Urban Hospital's 5 YEAR FTE TOTAL = 11.1
Second Rural Hospital's 5 YEAR FTE TOTAL (includes time at Second Rural Clinic) = 12.9
5 Year FTE Total = 24

Step 1: Highest number of FTE residents training in any program year during fifth year across all participating hospitals is 2.0:

PGY 1s = 2.0
PGY 2s = 2.0
PGY 3s = 2.0

Step 2: 2.0 × 3 (minimum accredited length) = 6.

Step 3: Urban Hospital's cap adjustment is based on the ratio of training at Urban Hospital over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [11.1/(24)] = 2.76.

Step 4: Second Rural Hospital's cap adjustment is based on the ratio of training at Rural Hospital and Rural Clinic over all 5 years to the total training that is occurring at all sites over all 5 years: 6 × [12.9/(24)] = 3.24

2.76 + 3.24 = 6.0, the total cap assignment does not exceed the total number of accredited slots. Urban Hospital's rural track FTE limitation is 2.76. *This second rural track FTE limitation is added to Urban Hospital's first rural track FTE limitation for a total rural track FTE limitation of 5.52 (2.76 + 2.76).* Second Rural Hospital's FTE cap adjustment is 3.24. *This second rural track FTE limitation is added to Second Rural Hospital's first rural track FTE limitation for a total rural track FTE limitation of 6.48 (3.24 + 3.24).* (We note that this calculation is done separately for IME and direct GME caps respectively. Also note that during these 5 program years, the hospitals exclude the FTE residents from the 3-year rolling average calculation on their Medicare cost reports.)

We are soliciting comments on our proposals.

c. Proposal for Implementation of Section 131 of the CAA, Addressing Adjustment of Low Per Resident Amounts (Direct GME) and Low FTE Resident Caps (Direct GME and IME) for Certain Hospitals

Section 131 of the CAA provides us with the opportunity to reset the low or zero direct GME per resident amount of certain hospitals, and to reset the low IME and direct GME FTE resident caps of certain hospitals. Regarding direct GME PRAs, as stated previously, section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period PRA that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983 through September 30, 1984). For hospitals that became teaching hospitals after 1984, section 1886(h)(2)(F) of the Act states that ''the Secretary shall, for the first such period for which it has such a residency training program and is participating under this title, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs. The regulations at 42 CFR 413.77(e)(1) implement this provision, stating that the per resident amount is based on the lower of the amount specified in paragraph (e)(1)(i) or paragraph (e)(1)(ii) of this section, subject to the provisions of paragraph (e)(1)(iii) of this section. In other words, the new teaching hospital's PRA generally will be based on the *lower of* its actual GME costs per FTE in its base period, or the weighted average PRA of existing teaching hospitals located in the same core-based statistical area (CBSA) as the new teaching hospital. Under section 1886(h)(2)(D) of the Act, once the PRA is established in a base period, no changes are made to it; it is only updated for inflation in each subsequent year.

The calculations of both direct GME payments and the IME payment adjustment are affected by the number of FTE residents that a hospital is

allowed to count. Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997.

(1) Background on Establishment of PRAs and FTE Resident Caps for Hospitals Hosting Residency Training

Section 1886(h)(2)(F) of the Act does not require a hospital to incur costs, be the program sponsor, or train a certain minimum number of FTE residents, in order to become a teaching hospital. Accordingly, under the regulations at 42 CFR 415.152, ''Teaching hospital'' is defined as a hospital engaged in an approved GME residency program in medicine, osteopathy, dentistry, or podiatry. Our historical policy is that if a hospital has residents that are training in an approved GME residency program(s), and if the training is according to a planned and regular schedule (that is, not spontaneous or random), then we consider the hospital to be a teaching hospital, even if—

- Is not incurring the costs of the residents' salaries and fringe benefits,
- It is not the sponsor of the program,
- It is not a ''new'' program under Medicare rules,

It is only training a very small number of FTE residents.

In the past, a number of hospitals have found themselves in the situation of triggering establishment of a PRA, when they have served as a training site for only small numbers of residents from programs sponsored by a medical school or another hospital. In many cases, these hospitals did not incur any salaries for those residents and may have incurred only insignificant overhead costs associated with the residents' presence at their facilities and, therefore, their PRAs were either very low or $0. Such low PRAs preclude meaningful direct GME payment in the future if these hospitals expand their training of residents and incur significant costs associated with the training. Section 131(a) of the CAA amends section 1886(h)(2)(F) of the Act to direct the Secretary, for such hospitals with such extremely low or $0 PRAs that meet certain criteria, to establish new PRAs using the methodology described in 42 CFR 413.77(e) if the hospital trains resident(s) in a cost reporting period beginning on or after its enactment (December 27, 2020) and before the date that is 5 years after enactment (December 26, 2025). In accordance with 42 CFR 413.77(e), a new teaching hospital's PRA is based on the *lower of* its actual GME costs per FTE, or the weighted average PRA of existing teaching hospitals located in the same core-based statistical area (CBSA) as the new teaching hospital.

With regard to hospitals that have triggered establishment of a very small number of permanent IME and direct GME FTE caps (but greater than zero), this establishment occurs when a hospital participates in training residents in a new program started or accredited on or after January 1, 1995. The statute directs the Secretary to prescribe rules for the application of the FTE resident caps for approved medical residency training programs established on or after January 1, 1995 at section 1886(h)(4)(H)(i) of the Act. The regulations at 42 CFR 413.79(l) defines a ''new medical residency training program'' as a medical residency that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995.'' Similar to the circumstances under which a PRA is triggered, the law does not state that in order to establish permanent FTE caps, a hospital must incur the cost of the new program, be the sponsor of the new program, or train a specific number of FTE residents in the new program. Some previously non-teaching hospitals have hosted small numbers of residents who were in programs sponsored and funded by a medical school or another hospital. If those residents rotating to the previously non-teaching hospitals were in a new approved program, then that could have triggered establishment of IME and direct GME FTE resident caps at the previously non-teaching hospital. Should the previously non-teaching hospital wish to participate in training residents in a significant manner in the future, such minimal FTE resident caps preclude receipt of meaningful IME and direct GME payments. Section 131(b) of the CAA addresses this problem by amending section 1886(h)(4)(H)(i) to add new subclauses (III) and (IV) to direct the Secretary, for hospitals that meet certain criteria and that have very small FTE resident caps, to ''adjust''—that is, redetermine those caps if the Secretary determines the hospital begins training residents in a program year beginning on or after enactment (December 27, 2020) and before 5 years after enactment (December 26, 2025).

(2) Hospitals Qualifying To Reset Their PRAs

Section 131(a) of the CAA also amends section 1886(h)(2)(F) of the Act to add a new clause (iii) to describe the categories of hospitals that qualify to receive a replacement PRA. For ease of reference, we will refer to these hospitals as Category A and Category B. A Category A Hospital is one that, as of the date of enactment (December 27, 2020), has a PRA that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997. Typically, a Category A hospital is one that trained less than 1.0 FTE in its most recent cost reporting period ending on or before December 31, 1996, and received a very low or $0 PRA. A Category B Hospital is one that, as of the date of enactment (December 27, 2020), has a PRA that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before the date of enactment (December 27, 2020). This new subclause provides that in lieu of these low PRAs, the Secretary shall, in accordance with § 413.77(e), establish a new PRA *for each such hospital if the hospital trains at least 1.0 FTE* (in the case of a Category A hospital) or *more than 3.0 FTE* (in the case of a Category B hospital) (emphasis added). The recalculation period begins on December 27, 2020, and ends 5 years later.

We are proposing that to redetermine the PRA, the training occurring at a Category A Hospital or a Category B Hospital need *not necessarily* be training residents in a *new* program; the residents may be in either an approved program that is ''new'' for Medicare IME and direct GME purposes, or may be in an existing approved program. This is because the new subclause does not state that the training be in a ''new'' program, and furthermore, CMS's current policy is that for a hospital which starts training residents for the first time, the PRA can be established based on the training of residents in either a ''new'' approved program, or an existing approved program. However, for a Category A Hospital, we propose not to reset its PRA until we determine that the Category A Hospital trains at least 1.0 FTE, and that training must occur in a cost reporting period

beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years after enactment). Similarly, for a Category B Hospital, we propose not to reset its PRA until we determine that the Category B Hospital trains more than 3.0 FTEs, and that training must occur in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and before December 26, 2025 (5 years after enactment). Because new section 1886(h)(2)(F)(iii) uses the word ''trains'', we interpret this to require ''continuous'' training, and therefore, we propose that for both Category A and B Hospitals, it is not relevant whether they may have trained at least 1.0 FTE or more than 3.0 FTEs in a cost reporting period or periods prior to December 27, 2020. While we propose that such previous training of at least 1.0 FTE or greater than 3.0 FTEs would not preclude resetting of a Category A Hospital's PRA or a Category B Hospital's PRA, we propose that the relevant factor in determining when to reset their PRAs is if and when the hospital trains the requisite amount of FTE residents in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and 5 years after (December 26, 2025). For example, a Category A Hospital trains 6.05 FTEs in its cost reporting period beginning on January 1, 2020. The Category A Hospital trains 5.95 FTEs in its cost reporting period beginning on January 1, 2021. We are proposing that we would reset this Category A Hospital's PRA effective with its cost reporting period beginning on January 1, 2021. In a second example, a Category B Hospital trains 6.05 FTEs in its cost reporting period beginning on January 1, 2020. The Category B Hospital trains 2.0 FTEs in its cost reporting period beginning on January 1, 2021. Then the Category B Hospital trains 3.25 FTE in its cost reporting period beginning on January 1, 2022. We are proposing that we would reset this Category B Hospital's PRA effective with its cost reporting period beginning on January 1, 2022. Once reset, in the absence of additional legislation, the PRAs for either a Category A Hospital or a Category B Hospital are permanent, subject to annual inflation updates under 42 CFR 413.77(c)(1).

(3) Proposal for How To Calculate the Replacement PRA and Cost Reporting Requirements

Consistent with the new statute, we propose to calculate the replacement PRA using the existing regulations in place at 42 CFR 413.77(e). First, we propose to use as the PRA base period the *first* cost reporting period in which either the Category A Hospital or Category B Hospital trains their requisite threshold FTEs; that is, the cost report beginning on or after December 27, 2020 in which at least 1.0 FTE is trained at Category A Hospital, and the cost reporting period beginning on or after December 27, 2020 in which more than 3.0 FTEs are trained at Category B Hospital. Then, as 42 CFR 413.77(e)(1) states, we propose to amend the regulations to add a new § 413.77(e)(1)(iv) to establish the replacement PRA as the LOWER OF:

- The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's replacement base year cost reporting period; and
- The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.
- If there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

We plan on issuing instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement PRAs. The MACs of the Category A and Category B Hospitals would review the Medicare cost reports, GME costs, FTE counts, rotation schedules, etc. to determine at what point the requisite threshold of FTE residents are trained. As required under 42 CFR 413.20 and 413.24, hospitals must provide sufficient documentation to ensure proper payment (for GME, this includes, but is not limited to, rotation schedules and training agreements). We note that newly amended section 1886(h)(2)(F) of Act makes two points regarding cost reporting. First, clause 1886(h)(2)(F)(ii) states that in the case of a hospital that trains residents and has not entered into a GME affiliation agreement (as defined by the Secretary for purposes of paragraph (4)(H)(ii)), on or after the date of enactment of this clause, the Secretary shall not establish an FTE resident amount until such time as the Secretary determines that the hospital has trained as least 1.0 FTE resident in an approved medical residency training program in a cost reporting period. Medicare GME affiliation agreements, as implemented in the regulations at 42 CFR 413.79(f), permit teaching hospitals that cross train residents in the same programs to aggregate and share their FTE resident caps to facilitate movement of residents and reimbursement for that training. Entering into a Medicare GME affiliation agreement is a voluntary and conscious action on the part of a hospital.

Therefore, even if a hospital trains less than 1.0 FTE (and this would be any hospital, not just a Category A Hospital or a Category B Hospital), but has entered into a Medicare GME affiliation agreement for that training, we believe the law is directing the Secretary to establish a PRA for that hospital. Thus, effective for a cost reporting period beginning on or after enactment (December 27, 2020), we are proposing to establish a PRA in the instance where a hospital trains *less than 1.0 FTE* and that hospital has entered into a Medicare GME affiliation agreement for that training. However, in the instance where a hospital did *not* enter into a Medicare GME affiliation agreement for that training, we propose to establish a PRA only when a hospital trains at least 1.0 FTE. We propose to amend the regulations at 42 CFR 413.79(f) to reflect this new provision.

Second, section 1886(h)(2)(F)(iv) states that for purposes of carrying out this subparagraph for cost reporting periods beginning on or after the date of the enactment of this clause, a hospital shall report full-time equivalent residents on its cost report for a cost reporting period if the hospital trains at least 1.0 full-time equivalent residents in an approved medical resident training program or programs in such period. Accordingly, we are proposing that both a Category A Hospital and a Category B Hospital must accurately report FTEs on the IME Worksheet E, Part A and the direct GME Worksheet E–4 of CMS-Form–2552–10, when *either category of hospital* trains at least 1.0 FTE on or after December 27, 2020. We are further proposing that *all* hospitals, even if they do not classify as Category A or Category B Hospitals, must enter the FTE counts on Worksheets E, Part A and E–4 of the CMS-Form–2552–10, for cost reporting periods during which the hospital trains at least 1.0. In addition, the hospital must provide the information required by the Interns and Residents Information System (IRIS) software for a cost report that contains at least 1.0 FTEs on Worksheets E, Part A (IME) and E–4 (direct GME). We are

proposing this rule regardless of whether or not such hospital incurs the costs or is the program sponsor, because we believe that a PRA is established when a hospital trains at least 1.0 FTE (or, if there is a Medicare GME affiliation agreement, even less than 1.0 FTE). We are proposing to amend the regulations at 42 CFR 413.78(b), with a cross-reference to 42 CFR 413.77(e) and 413.79(f), to require that effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if: (1) In the absence of a Medicare GME affiliation agreement, a hospital trains at least 1.0 FTE in an approved program or programs; or (2) if there is a Medicare GME affiliation agreement, a hospital trains less than 1.0 FTE in an approved program or programs. This proposed regulation would put hospitals on notice that they would establish a PRA when they report FTE residents on their Medicare cost report beginning on or after December 27, 2020.

On a technical note, newly added clause1886(h)(2)(F)(v) states that as appropriate, the Secretary may consider information from any cost reporting period necessary to establish a new FTE resident amount. Keeping in mind the regulations regarding predicate facts at 42 CFR 405.1885, our policy has been to refer, but not make changes, to a hospital's ''true'' base year under 42 CFR 413.77(e), even if that base year cost report is beyond the 3-year reopening rules. For example, if, in 2019, a MAC discovered that a hospital trained a small number of FTE residents in its 2005 cost reporting period, the MAC would use the 2005 cost report and documentation to obtain direct GME costs (if any, or $0) and the FTE resident(s), determine a cost per FTE, and compare that to the 2005 weighted average PRA of the other teaching hospitals in the same CBSA, even though the 2005 cost report was beyond the 3-year reopening period. In accordance with 42 CFR 413.77(e), the MAC would establish the LOWER of the two amounts to be the hospital's base year PRA. Going forward, we propose to continue to be consistent with our existing predicate fact regulations, such that we would not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation we would need to establish a PRA. However, because section 131 of the CAA directs the Secretary to replace a Category A Hospital's PRA or a Category B Hospital's PRA if the hospital trains at least 1.0 FTE or more than 3.0 FTE in a cost reporting period beginning on or after such date of enactment and before the date that is 5 years after, we are proposing to amend the regulations at 42 CFR 413.77(e) to use as the PRA base year for a Category A Hospital the cost reporting period beginning on or after December 27, 2020 and before December 26, 2025 in which that hospital trains at least 1.0 FTE, and for a Category B Hospital, the cost reporting period beginning on or after December 27, 2020 and before December 26, 2025 in which that hospital trains more than 3.0 FTEs. In determining whether a hospital trained the requisite thresholds of 1.0 or more than 3.0 FTEs, we propose not to round up; that is, an FTE count of 0.99 would not be rounded up to be at least 1.00 FTE. Rather, the FTE count would have to equal at least 1.00 without rounding applied. Similarly, an FTE count would have to add to be greater than 3.00 without rounding rules applied.

(4) Hospitals Qualifying To Reset Their FTE Resident Caps

Section 131(b) of the CAA 2021 amends section 1886(h)(4)(H)(i) of the Act to add new subclauses (II) through (V) to describe the categories of hospitals that qualify to receive a replacement PRA. For ease of reference, we continue to refer to these hospitals as Category A and Category B. A Category A Hospital is one that, as of the date of enactment (December 27, 2020), has an IME and/or direct GME FTE resident cap that was established based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997. Typically, a Category A hospital is one that did train less than 1.0 FTE in its most recent cost reporting period ending on or before December 31, 1996, and therefore, received FTE caps of less than 1.0 FTE (along with a very low or $0 PRA). Category B Hospital is one that, as of the date of enactment (December 27, 2020), has an IME and/or direct GME FTE resident cap that was established based on training of no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before the date of enactment (December 27, 2020). The new subparagraphs (III) and (IV) provide that the Secretary shall adjust the FTE resident cap in the manner applicable to a new approved medical residency training program, which under subparagraph (V), states that the adjustment to the FTE resident cap shall be made in a manner consistent with the methodology, as appropriate, in § 413.79(e). The Secretary shall adjust the FTE resident caps *if the hospital* ''*begins training*'' *at least 1.0 FTE* (in the case of Category A) or ''begins training'' *more than 3.0 FTE (*in the case of Category B) in a *program year* beginning on or after such date of enactment and before the date that is 5 years after such date of enactment (emphases added).

Unlike our preceding proposal regarding resetting the PRAs of Category A and B Hospitals, where a training program does not necessarily need to be new, in the case of resetting the FTE resident caps, we *are proposing* that the FTE resident caps would only be reset when a Category A Hospital or Category B Hospital ''begins training'' FTE residents in a new residency program(s) (see our discussion of the definition of ''new program'' at 42 CFR 413.79(l) and 74 FR 43908 through 43917). Specifically, we emphasize that the new subparagraphs (III) and (IV) state that the Secretary shall adjust the FTE resident caps in the manner applicable to a new program if the Secretary determines the hospital ''*begins training*'' the requisite number of FTE residents (emphasis added). We propose that ''begins training'' means *future* training in a new program *for the first time on or after enactment.* We propose that for both Category A and B Hospitals, it is not relevant whether they may have trained at least 1.0 FTE or more than 3.0 FTEs in a new program in a cost reporting period or periods prior to December 27, 2020; rather, we propose that the relevant factor in determining the timing of resetting their FTE resident caps is if the hospital *first begins training* the requisite amount of FTE residents at some point in a cost reporting period beginning on or after December 27, 2020 (date of enactment) and 5 years after (December 26, 2025). For example, a Category A Hospital trains 6.05 FTEs in a new program in its cost reporting period beginning on January 1, 2017. Category A Hospital trains 15.95 FTEs in its cost reporting period beginning on January 1, 2021. We are proposing that we would NOT reset this Category A Hospital's FTE resident caps effective with its cost reporting period beginning on January 1, 2021, because it first began training residents in a new program *prior* to its cost reporting period beginning on or after enactment, and continued to train FTE residents in the new program after enactment. Rather, in order to qualify for a replacement FTE resident cap, both a Category A Hospital and a Category B Hospital would have to wait to start training residents in a new program in a cost reporting period beginning on or after enactment; if they started training residents in a new program at some point *prior* to enactment, we are

proposing that they would not qualify to receive replacement FTE resident caps. For example, a Category A Hospital wanted to start training residents in a new program, but delayed doing so because it believed it could not support a new residency program with IME and direct GME FTE resident caps of less than 1.0. With the enactment of section 131 of the CAA, this Category A Hospital receives accreditation to start a new residency program, and begins to train at least 1.0 FTE residents in the new program on July 1, 2022. We propose to replace the small FTE resident caps of this Category A Hospital with new FTE resident caps in accordance with the regulations for calculating FTE resident caps for new programs at 42 CFR 413.79(e). We propose to apply the same policy for a Category B Hospital that waits to train more than 3.0 FTE residents in a new program in a cost reporting period on or after December 27, 2020.

(5) Proposal for How To Calculate the Replacement FTE Resident Caps and Cost Reporting Requirements

Consistent with the new statutory provisions, we would propose to calculate the replacement FTE resident caps using the existing regulations in place at 42 CFR 413.79(e)(1). First, we propose to use as the first program year of the 5-year cap building period in which either the Category A Hospital or Category B Hospital ''begins training'' their requisite threshold FTEs; that is, the program year beginning after December 27, 2020 in which at least 1.0 FTE begins to train at Category A Hospital, and the program year beginning after December 27, 2020 in which more than 3.0 FTEs are trained at Category B Hospital. Then, as 42 CFR 413.79(e)(1) states, we propose to calculate the FTE resident caps based on the sum of the products of the highest number of FTE residents in any program year during the fifth year of the first new program's existence and the number of years in which residents are expected to complete the program based on the minimum accredited length for each type of program. The adjustment to each qualifying hospital's cap for new residency training program (s) is equal to the sum of the products of—

- The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence at all of the hospitals to which the residents in the program rotate;
- The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.
- The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

We plan on issuing instructions to the MACs and to hospitals to provide for an orderly process of request and review for the purpose of receiving replacement FTE resident caps. The MACs of the Category A and Category B Hospitals would review the Medicare cost reports (including rotation schedules, information regarding any nonprovider-site training, and accreditation information, etc.) to determine at what point the requisite threshold of FTE residents would be trained. As required under 42 CFR 413.20 and 413.24, hospitals must provide sufficient documentation to ensure proper payment (for GME, this includes, but is not limited to, rotation schedules and training agreements, and ACGME accreditation information).

Prospectively, consistent with new section 1886(h)(4)(H)(i)(II) of the Act, we propose not to establish permanent FTE resident caps for hospitals training residents in new programs begun on or after December 27, 2020, until we determine that in a cost reporting period beginning on or after December 27, 2020, the hospital trains at least 1.0 FTE in a new medical residency program. We propose to amend the regulations at 42 CFR 413.79(e) to reflect this new provision. We are proposing this for all hospitals that do not yet have caps triggered. Therefore, permanent FTE caps for new programs would no longer be triggered if the amount of FTEs being trained by a hospital in the new program equates to less than 1.0 FTE.

As with the resetting of the PRAs, newly added section 1886(h)(4)(H)(i)(V) states that as appropriate, the Secretary may consider information from any cost reporting period necessary to make such an adjustment to the limitation. Going forward, we propose to continue to be consistent with our existing predicate fact regulations at 42 CFR 405.1885, such that we would not reopen cost reports beyond their 3-year reopening period, but would refer to and use whatever contemporaneous documentation we would need to establish the FTE resident caps.

We are soliciting comments on our proposals regarding resetting the applicable PRAs and FTE resident caps.

d. Proposal for Intern and Resident Information System (IRIS) Data

Section 42 CFR 413.24(f)(5)(i) provides that a Medicare cost report for a teaching hospital is rejected for lack of supporting documentation if the cost report does not include a copy of the Intern and Resident Information System (IRIS) diskette. In accordance with 42 CFR 413.78(b) for direct GME and 2 CFR 412.105(f)(1)(iii)(A) for IME, no individual may be counted as more than one full-time equivalent (FTE). A hospital cannot claim the time spent by residents training at another hospital; if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as a partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of total time worked compared to the total time necessary to fill a full-time internship or residency slot.

In 1990, we established the IRIS, under the authority of sections 1886(d)(5)(B) and 1886(h) of the Act, in order to facilitate proper counting of FTE residents who rotate to more than one site (that is, hospitals, non-provider settings). Teaching hospitals use the IRIS to collect and report information on residents training in approved residency programs. Section 42 CFR 413.24(f)(5)(i) requires teaching hospitals to submit the IRIS data along with their Medicare cost reports in order to have an acceptable cost report submission. We are in the process of issuing a new Extensible Markup Language (XML)-based IRIS file format that captures FTE resident count data consistent with the manner in which FTEs are reported on the Medicare cost report.

After receiving the IRIS data along with each teaching hospital's cost report, the contractors upload the data to a national database housed at CMS, which can be used to identify ''duplicates,'' that is, the same time period (for example, April 1 through April 3 of a given fiscal year) being claimed by more than one hospital in their GME/IME FTE resident count. If duplicates are identified, the contractors will make the hospitals that claimed the same time aware of this situation and will correct the duplicate reporting on the respective hospitals' cost reports for direct GME and IME payment purposes.

Historically, we would collect the IRIS data from hospitals on a diskette, as referenced in 42 CFR 413.24(f)(5)(i). Because diskettes are no longer used by providers to furnish these data to contractors, in this proposed rule, we are proposing to remove the reference in

the regulations to a diskette and instead reference ''Intern and Resident Information System data.'' Specifically, we are proposing to amend 42 CFR 413.24(f)(5)(i) by adding a new paragraph (A) to include this proposed revised language.

In addition, to enhance the contractors' ability to review duplicates and to ensure residents are not being double-counted, we believe it is necessary and appropriate to require that the total weighted and unweighted FTE counts on the IRIS for direct GME and IME respectively, for all applicable allopathic, osteopathic, dental, and podiatric residents that a hospital may train, must equal the same total weighted and unweighted FTE counts for direct GME and IME reported on Worksheet E–4 and Worksheet E, Part A of the filed Medicare cost report. The need to verify and maintain the integrity of the IRIS data has been the subject of reviews by the Office of the Inspector General (OIG) over the years. An August 2014 OIG report cited the need for CMS to develop procedures to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–13–01014, August 2014). More recently, a July 2017 OIG report recommended that procedures be developed to ensure that no resident is counted as more than one FTE in the calculation of Medicare GME payments (OIG Report No. A–02–15–01027, July 2017).

Therefore, effective for cost reporting periods beginning on or after October 1, 2021, we are proposing to add the requirement that IRIS data contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME and IME FTE residents reported in the cost report. Specifically, we are proposing to amend 42 CFR 413.24(f)(5)(i) to state that, effective for cost reporting periods on or after October 1, 2021, the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report, or the cost report will be rejected for lack of supporting documentation.

Providers would be required to use the new XML IRIS format for all cost reports with cost reporting periods beginning on or after October 1, 2021. CMS does not have a free download of the new IRIS XML format; the providers should use their vendors' software to file their IRIS report with the Medicare Administrative Contractor.

K. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years: These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) (Affordable Care Act), section 15003 of the 21st Century Cures Act (Pub. L. 114–255)(Cures Act), enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) (CAA 2021). In this proposed rule, we are summarizing the status of the demonstration program, and proposing the methodologies for continued implementation and budget neutrality under the extension authorized by section 128 of the Public Law 116–260.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

3. Proposed Policies for Implementing the 5-Year Extension Period Authorized by Public Law 116–260

Our policy for implementing the 5-year extension period authorized this year by Public Law 116–260 follows upon that for the previous extensions, under the Affordable Care Act (Pub. L. 111–148) and the Cures Act (Pub. L. 114–255).

Section 410A of Public Law 108–173 (MMA) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 (Affordable Care Act) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during this 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30.

Section 15003 of the Cures Act required the Secretary to conduct the demonstration for a 10-year extension period (in place of the 5-year extension period required by Public Law 111–148 (Affordable Care Act)). Specifically, section 15003 of Public Law 114–255 (Cures Act) amended section 410A(g)(4) of Public Law 108–173 (MMA) to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary would provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital made an election, in such form and manner as the Secretary may specify, to discontinue participation. In addition, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary would apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period

and payment for services provided under the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Pub. L. 114–255) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 (Affordable Care Act) elected to continue in the 5-year extension period authorized by Public Law 114–255 (Cures Act). Therefore, for these hospitals, this third 5-year period of participation started on dates ranging from May 1, 2015 through January 1, 2017, depending on when they had initially started. On November 20, 2017, we announced that 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (These two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost-reporting period on or after October 1, 2017. One of the newly participating hospitals withdrew from the demonstration program prior to beginning participation in the demonstration on July 1, 2018. In addition, one of the previously participating hospitals closed effective January 2019, and another withdrew effective October 1, 2019. Therefore, 27 hospitals were participating in the demonstration as of this date—15 previously participating and 12 newly participating.

Each hospital has had its own end date applicable to this third five-year period for the demonstration. For four of the previously participating hospitals, this end date fell within FY2020, while for 11 of the previously participating hospitals, the end date would fall within CY 2021. (One of the hospitals within this group chose in February of 2020 to withdraw effective September of the previous year). The newly participating hospitals were all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

Division CC, section 128 of CAA 2021 requires a 15-year extension period (that is, an additional five years beyond the current extension period), to begin on the date immediately following the last day of the initial 5-year period, instead of the 10-year extension period mandated by the Cures Act. In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. We, therefore, interpret the statute as providing for an additional 5-year period under the reasonable cost-based reimbursement methodology for the demonstration for the hospitals that were participating as of this date.

Given that four hospitals ended the 5-year period authorized by the Cures Act during FY 2020, we propose to keep to the policy finalized for the previous extensions, and apply the cost-based reimbursement methodology to the date following the last day of this previous period for each hospital that elects to continue participation. Likewise, each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023 and the hospital that withdrew in February 2020 will be eligible for an additional 5-year period starting from the day after the specified end date. Accordingly, the period of participation for the last hospital in the model under this most recent legislative authorization would extend until June 30, 2028.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, makes it unlikely that increased Medicare outlays will produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. We note that we have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by CAA 2021

For the newly enacted extension period, under CAA 2021, we propose to continue upon the general budget neutrality methodology used in previous years, and specifically to follow upon the determinations for the previous extension period, under the Cures Act.

(1) Budget Neutrality Methodology for Previous Extension Period Under the Cures Act

We finalized our budget neutrality methodology for periods of participation under this previous 5-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in this rule, as well as in the FY 2019 and FY 2020 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, and 84 FR19452 and 42421, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals, and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports, when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In these proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by the Cures Act.

We included a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In the FY 2020 IPPS final rule (84 FR 42421), we included an estimate of the costs of the demonstration for FY 2020 for 28 hospitals. In the FY 2021 IPPS final rule (85 FR 58873), we included an estimate of the costs of the demonstration for FY 2021 for the 22 hospitals for which the cost-based reimbursement methodology was to apply for all or part of FY 2021.

Similar to previous years, we continued to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that decided to participate in the 5-year extension period under the Cures Act, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the still previous extension period (under the Affordable Care Act). In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). In the FY 2020 final rule, we included the difference between the amount determined for the cost of the demonstration in each of FYs 2014 and 2015 and the estimated amount included in the budget neutrality offset in the final rule for each of these respective fiscal years. For FY 2016 and subsequent years, we will use finalized cost reports when available that detail the actual costs of the demonstration for each of these fiscal years and incorporate these amounts into the budget neutrality calculation.

(2) Methodology for Estimating Demonstration Costs for FY 2022

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2022. We are conducting this estimate for FY 2022 based on the 27 hospitals that are eligible to continue participation in demonstration for the fiscal year. The methodology for calculating this amount for FY 2022 proceeds according to the following steps:

Step 1: For each of these 27 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is that with cost report period end date in CY 2019. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 27 hospitals eligible to participate during FY 2022.

Then, we multiply this amount by the FYs 2020, 2021 and 2022 IPPS market basket percentage increases, which are calculated by the CMS Office of the Actuary. (We are using the proposed market basket percentage increase for FY 2022, which can be found in section II.A. of the addendum to this proposed rule). The result for the 27 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2022.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2020 through 2022 to the applicable estimated reasonable cost amount (previously described) in order to model the estimated FY 2022 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2022 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2020, 2021 and 2022 IPPS applicable percentage increases. (For FY 2021, we are using the proposed applicable percentage increase, per section II.A. of the Addendum of this proposed rule).This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS

payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 27 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2022. For this proposed rule, the resulting amount is $63,829,479, which we are incorporating into the budget neutrality offset adjustment for FY 2022. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. If updated data become available prior to the final rule, we will use them as appropriate to estimate the costs for the demonstration program for FY 2022 in accordance with our methodology for determining the budget neutrality estimate).

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2015 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

In the FY 2021 proposed rule, we stated that if finalized cost reports for the entire set of hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016 were available by the time of the final rule, we would include in the final budget neutrality offset amount the difference between the actual cost as determined from these cost reports and the estimated amount in the FY 2016 final rule.

When the complete set of finalized cost reports were not available for the FY 2021 final rule, we stated that we would aim to include this difference within the FY 2022 proposed and final rules. At this time still, all of the cost reports have not been finalized for the 18 hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016. If the entire set of finalized cost reports is available in time for the FY 2022 final rule, we will be able to incorporate this amount in the overall budget neutrality offset amount.

(4) Total Proposed Budget Neutrality Offset Amount for FY 2022

Therefore, for this FY 2022 IPPS/LTCH PPS proposed rule, the budget neutrality offset amount for FY 2022 is based on the amount determined under section V.K.c.(2). of the preamble of this proposed rule, representing the difference applicable to FY 2022 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 27 hospitals eligible to participate in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $63,829,479. We propose to subtract this amount from the national IPPS rates for FY 2022. We note, however, that the overall amount might change if there are any revisions prior to the final rule to the data used to formulate this estimate. In addition, if the entire set of finalized cost reports for FY 2016 is available ahead of the final rule, we will also include this amount within the total budget neutrality offset amount to be applied to the FY 2022 national IPPS rates.

L. Market-Based MS–DRG Relative Weight Policy—Proposed Repeal (§ 413.20)

1. Overview

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021 (85 FR 58873 through 58892); this data collection requirement is specified in 42 CFR 413.20(d)(3). We also finalized the use of this data in a new market-based methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing, beginning in FY 2024. Specifically, we finalized that we will begin using the reported median payer-specific negotiated charge by MS–DRG for MA organizations in the market-based MS–DRG relative weight methodology beginning with the relative weights calculated for FY 2024.

2. Proposed Repeal of the Market-Based MS–DRG Relative Weight Data Collection and Market-Based Methodology for Calculating MS–DRG Relative Weights

After further consideration of the many contract arrangements hospitals use to negotiate rates with MA organization payers, and the usefulness, for ratesetting purposes, of the market-based data as reported in accordance with the FY 2021 IPPS/LTCH PPS final rule, we are proposing to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021. We are also proposing to repeal the market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, and to continue using the existing cost-based methodology for calculating the MS–DRG relative weights for FY 2024 and subsequent fiscal years. Comments received on the 60-day Paperwork Reduction Act (PRA) revision request of the information collection requirement (ICR) (approved under OMB control number 0938–0050, expiration date March 31, 2022, published on November 10, 2020 (85 FR 71653 and 71654)), also provided further questions for us to examine regarding the usefulness of this data, and requested that we consider a delay or repeal of this policy. In light of these questions and for the reasons discussed, we are proposing to repeal the market-based data collection and MS–DRG relative weight methodology to allow for further consideration of these questions and possible alternative approaches.

We also propose to amend 42 CFR 413.20(d)(3) to reflect the proposed repeal of the market-based MS–DRG relative weight data collection requirement. Specifically, we propose to amend 42 CFR 413.20(d)(3) to remove the requirement at 42 CFR 413.20(d)(3)(i)(B) that a provider furnish the contractor its median payer-specific negotiated charge by MS–DRG for payers that are MA organizations, as applicable, and changes thereto as they are put into effect, and to renumber the existing provisions accordingly.

In light of this proposal to repeal the requirement for hospitals to report this median payer-specific negotiated charge data on the cost report, we will revise the forthcoming revision of the Information Collection Request currently approved under OMB control number 0938–0050, expiration date March 31, 2022, accordingly.

We are inviting public comment on our proposal to repeal the market-based data collection requirement and market-based MS–DRG relative weight methodology. We also invite public comment on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) ratesetting.

M. Payment Adjustment for CAR T-cell Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58599 through 58600), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. We refer the reader to section II.D.2. of this proposed rule for discussion of the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies that we are proposing for assignment to MS–DRG 018 for FY 2022. In the FY 2021 IPPS/LTCH PPS final rule, we modified our relative weight methodology for MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, we finalized to not include claims determined to be clinical trial claims that group to new MS–DRG 018 when calculating the average cost for new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600).

In the FY 2021 IPPS/LTCH PPS final rule, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that would group to MS–DRG 018 (85 FR 58842) using the same methodology that we used to adjust the case count for purposes of the relative weight calculations. Specifically, after consideration of public comments, we finalized our proposal to apply a payment adjustment to claims that group to new MS–DRG 18 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. We codified this payment adjustment at 42 CFR 412.85 (for operating IPPS payments) and 42 CFR 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, including to reflect that the adjustment will also be applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. We also finalized our regulations at 42 CFR 412.85(c) to reflect that the adjustment factor will reflect the average cost for cases to be assigned to MS DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial. (85 FR 58844).

Using the same methodology from the FY 2021 IPPS/LTCH PPS final rule, we are proposing to apply an adjustment to the payment amount for clinical trial cases that would group to MS–DRG 018 (85 FR 58842), which is the same methodology we are proposing to use to adjust the case count for purposes of the relative weight calculations:

- Calculate the average cost for cases to be assigned to MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

Additionally, we are continuing our finalized methodology for calculating this payment adjustment, such that: (a) When the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases. However, we continue to believe to the best of our knowledge there are no claims in the historical data (FY 2019 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

Consistent with our calculation of the adjustor for the relative weight calculations, and our proposal to use the FY 2019 data for the FY 2022 ratesetting, we are proposing to continue to calculate this adjustor based on the March 2020 update of the FY 2019 MedPAR file for purposes of establishing the FY 2022 payment amount. Specifically, we are proposing to multiply the FY 2022 relative weight for MS–DRG 018 by an adjustor of 0.17 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018, which under our proposal includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We refer the reader to section II.D.2. for a further discussion of MS–DRG 018. As discussed in section I.F. of this proposed rule, we are also soliciting comments on an alternative approach of using the same FY 2020 data that we would ordinarily use for purposes of the FY 2022 rulemaking, which we may consider finalizing for FY 2022 based on consideration of comments received. We note that using the methodology as finalized in the FY 2021 IPPS/LTCH PPS final rule, we calculated an adjustor of 0.25 based on this alternative approach of using the FY 2020 MedPAR file.

VI. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in

establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Proposed Annual Update for FY 2022

The proposed annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2022 is discussed in section III. of the Addendum to this FY 2022 IPPS/LTCH PPS proposed rule.

In section II.C. of the preamble of this FY 2022 IPPS/LTCH PPS proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are proposing for FY 2022, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not proposing to make a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

We also note that in section IV.G. of the preamble of this proposed rule, we discuss our proposed adjustment to the payment amount for certain clinical trial or expanded access use immunotherapy cases that will group to MS–DRG 018 for both operating IPPS payments and capital IPPS payments. We refer readers to section IV.G. of this preamble for additional details on the proposed payment adjustment for these cases.

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2022

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious

nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short–term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. As discussed in section IV. of the preamble of this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to rebase and revise the IPPS operating basket to a 2018 base year. Therefore, we are proposing to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2022 percentage increase in the proposed 2018-based IPPS operating market basket.

For this FY 2022 IPPS/LTCH PPS proposed rule, based on IGI's 2020 fourth quarter forecast, we estimate that the proposed 2018-based IPPS operating market basket update for FY 2022 would be 2.5 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2022 rate-of-increase percentage that would be applied to the FY 2021 target amounts in order to calculate the FY 2022 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 2.5 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the FY 2022 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2022.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2022, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2022, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2022, which would be equal to the percentage increase in the hospital market basket, which is estimated to be the percentage increase in the proposed 2018-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2022 is 2.5 percent, which is based on IGI's 2020 fourth quarter forecast. Furthermore, we are proposing that if more recent data become available for the FY 2022 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2022.

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

a. Background and Overview

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58896), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee

under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limited participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 required the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, we released a request for applications (RfA) for the FCHIP Demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as states meeting the statutory eligibility requirement for participation in the demonstration. The RfA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RfA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RfA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016, and concluded on July 31, 2019 (referred to in this section as the ''initial period''). The selected CAHs were located in Montana, Nevada, and North Dakota, and participated in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58896). Eight CAHs participated in the telehealth intervention, three CAHs participated in the skilled nursing facility/nursing facility bed intervention, and two CAHs participated in the ambulance services intervention. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention included in the RfA.

b. Intervention Payment and Payment Waivers

CMS waived certain Medicare rules for CAHs participating in the demonstration to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: Telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only applied if the CAH participated in the associated intervention. The FCHIP payment waivers consisted of the following:

(1) Telehealth Services Intervention Payments

CMS waived section 1834(m)(2)(B) of the Social Security Act (the Act), which specifies the facility fee to the originating site (that is, the participating CAH where the eligible telehealth individual is located). CMS modified the facility fee payment specified under section 1834(m)(2)(B) of the Act to allow for reasonable cost-based reimbursement to the participating CAH. CMS reimbursed the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries, fringe benefits, and the depreciation value of the telehealth equipment at the participating CAH. The Demonstration waiver did not fund or provide reimbursement for the participating CAHs to purchase new telehealth equipment. However, if a participating CAH purchases new equipment, CMS would continue to reimburse depreciation costs for that equipment. The payments to the distant site physician or practitioner were made as usual under the Medicare physician fee schedule. CMS did not waive any other provisions of section 1834(m) of the Act, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

(2) Ambulance Services Intervention Payments

CMS waived 42 CFR 413.70(b)(5)(C), which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services if the CAH or entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH. Under the demonstration, a participating CAH was paid 101 percent of reasonable costs for its ambulance services regardless of whether there was any other provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or CAH-owned and operated entity. Cost-based payment was not allowed for any new capital expenditures (for example, vehicles) associated with ambulance services. This waiver did not modify any other Medicare rules affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waived 42 CFR 485.620(a) and 42 CFR 485.645(a)(2), which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. Through this waiver, CAHs participating in the SNF/NF intervention were allowed to keep up to 10 additional beds (for a total of up to 35 beds) available for acute inpatient or swing bed services; however, the participating CAHs were only to use these additional beds for nursing facility or skilled nursing facility level of care. SNF/NF services furnished in the additional beds were reimbursed according to the standard Medicare reimbursement principles for CAHs. Additional capital expenditures were not allowed under this waiver. No changes to the methodology for calculating Medicare payments for swing bed services at participating CAHs were allowed. The Conditions of Participation (CoPs) for certified critical access hospitals providing (SNF/NF) long term care services are at 42 CFR 485.645. Certification to participate in Medicare's swing bed program is a

separate approval by CMS from the certification to operate as a CAH provider of services. The participating CAHs within the SNF/NF Beds Expansion intervention were required to receive approval from and be certified by CMS to participate in the Demonstration swing bed program.

c. Budget Neutrality Requirement

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we finalized a policy to address the budget neutrality requirement for the demonstration. We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 through 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58894 through 58996), but did not make any changes to the policy that was adopted in FY 2017. As explained in the FY 2017 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we adopted in the FY 2017 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we stated that we would comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the FCHIP Demonstration was projected to satisfy the budget neutrality requirement and likely yield a total net savings. In the FY 2017 IPPS/LTCH PPS (81 FR 57064 through 57065) final rule, we estimated that the total impact of the payment recoupment (if needed) would be no greater than 0.03 percent of CAHs' total Medicare payments (that is, Medicare Part A and Part B) within 1 fiscal year. We also explained that the final budget neutrality estimates for the FCHIP Demonstration would be based on costs incurred during the initial period of the demonstration from August 1, 2016, through July 31, 2019.

d. FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2021 IPPS/LTCH PPS final rule, our goal was to maintain the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments to the participating CAHs resulting from the demonstration). The analysis of budget neutrality identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2021 IPPS/LTCH PPS final rule (85 48432 through 59107), we computed the cost of the demonstration for each fiscal year of the demonstration period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

e. General Analytical Approach

The budget neutrality assessment sought to determine if the goal to maintain budget neutrality of the demonstration on its own terms was met. We examined the difference in expenditures for groups of beneficiaries who received intervention services at demonstration CAHs or at comparison CAHs that were not participating in the demonstration. The demonstration and comparison groups were composed of Medicare beneficiaries receiving an intervention service (that is, telehealth, SNF/NF or ambulance) at participating CAHs and non-participating CAHs, respectively. To ensure that there was no cross contamination between the two groups, the demonstration and comparison groups were mutually exclusive of each other, and beneficiaries who received intervention services at both participating and non-participating CAHs were included within the demonstration group only.

Medicare reimbursement for the demonstration intervention services depended on the service provided. For the swing bed services, the demonstration CAH swing bed reimbursement was based on 101 percent of the reasonable cost of the SNF services furnished in the swing beds (as computed in the Medicare cost report). The CAHs were paid on an interim basis using a per diem rate for routine and ancillary costs. For the demonstration ambulance and telehealth services, CAH reimbursement was based on 101 percent of the reasonable cost of providing the services to Medicare patients (as computed in the Medicare cost report). The CAHs were paid on an interim basis using a percentage of Medicare charges. The applicable percentage of Medicare charges was calculated by dividing the overall allowable Medicare costs by the overall Medicare charges in order to determine the Medicare cost-to-charge ratio.

The three intervention services were different, and each demonstration CAH had the option to implement one, two or all three interventions. Therefore, budget neutrality was analyzed for each demonstration intervention service separately. The basic approach to the analysis was similar for each intervention service, but some additional variables were incorporated

based on the nature of the intervention and its expected impact. The findings for each intervention service were then combined at the end of the process to reach a single conclusion regarding budget neutrality for the initial period of the demonstration as a whole.

f. Data Elements

Beginning with the cost report data, CMS conducted Medicare cost report audit reviews for the 10 participating CAHs over the course of the three-year demonstration period. The cost reports are a collection of worksheets that calculate the costs of a specific provider for supplying health care services to Medicare beneficiaries and when aggregated these cost reports furnish information used by researchers, actuaries and policy makers. All CAHs participating in the Medicare program are required to submit cost reports annually, with the reporting period based on the provider's accounting year. It should be noted the FCHIP Cost Report audits calculated budget neutrality as determined only by the change in the cost of providing services to Medicare beneficiaries through the Medicare cost report and excluded other factors that may also influence aggregate cost to the Medicare program, such as a shifting of essential services to CAHs from more expensive tertiary hospitals or other downstream cost impacts.

The intervention services authorized under the demonstration may impact cost in several ways that can act to either increase or decrease expenditures. For example, the transition from a facility fee payment to the originating site to cost-based reimbursement under the telehealth services intervention would likely result in increased costs for those services. However, the Medicare administrative claims analysis anticipated and measured that telehealth intervention services furnished under the demonstration may also produce savings through better management of chronic conditions, reduction in air transports, and reduction in transfers to other and/or more expensive facilities. In general, the intervention services under the demonstration may affect access to services and referral patterns that, in turn, may affect utilization and therefore costs. In order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DID) regression analysis to estimate demonstration episode expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the 36-month period of performance under the initial period of demonstration. Analyses were conducted separately for each intervention service using regression-based methods that controlled for demographics, diagnostic conditions, hierarchical condition categories (HCC) risk scores, and other factors. Results were combined across the three intervention services to produce a summary conclusion regarding budget neutrality for the initial period of the demonstration as a whole.

This general analytic approach involved the comparison of total episode expenditures for beneficiaries receiving intervention services from CAHs in the demonstration group to the expected expenditures absent the demonstration. The projection of expected expenditures absent the demonstration included an additional adjustment to reflect the statistical uncertainty of the predictions. If actual expenditures for the intervention services furnished by CAHs in the demonstration group exceeded the expected expenditures absent the demonstration (with the adjustment for statistical uncertainty), then budget neutrality could potentially be violated. CMS conducted a series of analytical steps as previously described to determine the budget neutrality outcome for the initial period of the demonstration.

g. Methodology for Estimating Demonstration Costs

Step 1: The Medicare cost reports for CAHs participating in the FCHIP Demonstration were reviewed to verify reasonableness of reported expenses, revenues and statistics and to ensure the reported demonstration expenses were allowable and accurately allocated on the cost report. CMS performed a reasonableness analysis of the cost reports for each of the demonstration CAHs that focused on cost incurred by the CAH to determine whether the costs were necessary and proper for patient care under the demonstration. CMS also performed an allowability analysis for each demonstration CAH to determine which costs were directly related to the demonstration and to ensure all reported costs related to the intervention services were accounted for. In addition, each demonstration CAH's cost reports were audited to ensure the reported expenses were allowable and accurately allocated to each intervention service considering established Medicare regulations as modified by demonstration requirements. Demonstration costs that were unrelated to patient care were deemed not allowable. The cost report audit analysis included removal of any cost claimed by demonstration CAHs that was not specifically described in '(b) Intervention Payment and Payment Waivers', which describes the Medicare rules and payments methods that were actually made under the demonstration for each of the three interventions.

For each of the 10 demonstration CAHs, we identified the reasonable cost amount calculated under the reasonable cost-based methodology for the demonstration covered inpatient hospital services and covered outpatient hospital services, including swing bed, telehealth, and ambulance services as indicated on the ''as submitted'' cost report for each hospital cost reporting period covering the initial period of performance for the demonstration from August 1, 2016, through July 31, 2019. For each of the demonstration CAHs, these ''as submitted'' cost reports are those with cost report period end dates in Calendar Year (CY) 2016, 2017, 2018, 2019 and 2020. We note that among the demonstration CAHs with ''as submitted'' cost reports in CY 2020, the cost reporting period covered January 1, 2019, to December 31, 2019; March 1, 2019, to April 30, 2020; or July 1, 2019, to June 30, 2020.

Step 2: CMS utilized Hospital 2552–10 Cost Report Data files to calculate the change in Medicare reimbursement for the initial period of performance. CMS calculated Medicare reimbursement costs under the demonstration versus Medicare reimbursement costs without the demonstration. ''Medicare reimbursement costs without the demonstration'' were defined as Medicare costs as determined using the Medicare payment methodologies that would have applied absent the demonstration and represented the baseline costs for each intervention service. ''Medicare reimbursement costs under the demonstration'' were defined as the costs as determined through the audited cost report after the application of the demonstration payment waiver methodologies. The difference between these costs represented the cost impact of the demonstration.

For each of the participating CAHs, we identified the estimated amount that would otherwise be paid under applicable Medicare payment methodologies for covered intervention services (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. (Also, as indicated on the same set of ''as submitted'' cost reports as in Step 1), we identified the estimated amount that was paid for

covered intervention services under the demonstration. To compute the aggregate change in cost due to the demonstration, we calculated the difference in the costs of intervention services between ''Medicare reimbursement costs without the demonstration'' versus ''Medicare reimbursement costs under the demonstration'' from the cost reports.

Step 3: For each of the 10 CAHs, Medicare administrative claims and enrollment data for beneficiaries receiving demonstration intervention services were identified. The data were collected at the individual beneficiary level and included information on service type, service date, and reasonable cost payment amount calculated under the reasonable cost-based methodology for covered intervention services furnished under the demonstration. Codes indicating diagnosis and the specific procedure provided under the demonstration were also identified using the claims and enrollment data and were used in the analysis.

Step 4: CMS defined ''episodes of care'' for the eligible CAHs. For each of the participating CAHs, using Medicare administrative claims, we identified costs related to providing demonstration intervention services. The demonstration CAHs submitted Medicare claims for the demonstration intervention services. These claims were consolidated by the Medicare Administrative Contractor (MAC) into interim payments, which were incorporated into an episode of care framework for purposes of the budget neutrality calculation. CMS defined an episode of care as all Medicare Parts A and B services furnished to a beneficiary receiving a demonstration intervention service during a specified period of time ranging from 30 to 60 days following the receipt of a demonstration intervention service. The specific timeframes for the episodes of care were chosen for each intervention based on observed expenditure patterns following an episode-triggering intervention service.

Episode costs were defined as the cost of all Medicare Parts A and B services provided to the beneficiary during the episode. Next, CMS incorporated the claims and interim payment data into the episode of care framework.

Step 5: CMS constructed Episode of Care Comparison groups and potential savings variables. We separated the episode of care Medicare Parts A and B expenditures into two groups—expenditures for beneficiaries receiving intervention services from demonstration group CAHs and expenditures for beneficiaries receiving intervention services from non-demonstration (comparison) group CAHs within the FCHIP eligible States (Montana, Nevada, and North Dakota). Then we compared episode of care expenditures for beneficiaries receiving intervention services from demonstration group CAHs to those for beneficiaries receiving intervention services from comparison group CAHs.

Step 6: CMS conducted the Difference-in-Difference Analysis. Using the episode of care framework described in Step 4, the demonstration and comparison groups were used to measure the impact of the intervention services on episode expenditures through a DID analysis comparing baseline and performance period(?) costs for the demonstration groups and comparison groups. The DID regression model was estimated using episode expenditures as the dependent variable. (The model's functional form was a generalized linear model with a log link and gamma distribution. This type of model is commonly used in analyzing health care expenditures and yields only positive predicted values.) All analyses were carried out separately for the three intervention services. Using the episode of care approach enabled us to identify downstream effects of the intervention services, including any savings that may have accrued. For each of the participating CAHs we identified cost-savings or reductions in transfers and admissions to other health care providers, offsetting any increase in Medicare payments that may have resulted from the use of intervention services. Results were combined across the ten CAH participants and across the three interventions to produce a summary conclusion regarding budget neutrality for the 36-month initial demonstration performance period.

Step 7: Lastly, CMS performed a supplementary sensitivity analysis adjustment for statistical uncertainty. The DID analysis results obtained using the Medicare administrative claims data were then reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. The Medicare cost reports provide another source of data related to demonstration expenditures beyond the information that is directly reported via Medicare administrative claims. The Medicare cost report audit findings were used to reconcile the directionality and outcome of the DID regression analysis results. The sensitivity analysis was calculated for the demonstration as a whole to ensure the budget neutrality conclusion via the DID analysis was not the result of random variation or statistical uncertainty of the predictions used in the analysis.

g. Budget Neutrality Conclusion

Based on analysis of the Medicare administrative claims data and the Medicare cost report audit data from the 36 months of the initial demonstration performance period, there were no statistically significant findings that the FCHIP Demonstration resulted in additional expenditures. The DID analysis results were based on an episode of care point estimate threshold. If the actual episode expenditures of the demonstration exceeded the expected expenditures absent the demonstration (with the sensitivity analysis adjustment for statistical uncertainty) then the requirement for budget neutrality under section 123(g)(1)(B) of Public Law 110–275 could potentially be violated. CMS found in aggregate that the demonstration CAHs' episode of care expenditures during the initial period of the demonstration were lower than expenditures would have been absent the demonstration. In fact, when the sensitivity analysis (using a 95 percent confidence interval) was calculated it showed that total expenditures for the 10 participating CAHs in the demonstration would need to cumulatively increase cost by more than 18 percent (which translated to $3,120 per episode, or a total of $3,529,039 for the three interventions combined) to exceed expenditures absent the demonstration. When we compared the total cost of Medicare episodes of care under the demonstration with the aggregate demonstration cost findings based on the audit of Medicare cost reports, we also found that the aggregate demonstration intervention services cost on the ''as submitted'' Medicare cost reports fell within the point estimate threshold—therefore, the FCHIP Demonstration did not result in additional expenditures during the initial period of the demonstration.

Under the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58895), we stated that based on the currently available data, the determination of budget neutrality results was preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remained uncertain. Therefore, we revised the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any

budget neutrality adjustment and stated that we would revisit this policy in rulemaking for FY 2022, when we expected to have complete data for the demonstration period. Based on the data and actuarial analysis described previously, we have concluded that the initial period of the FCHIP Demonstration (covering the performance period August 1, 2016, to July 31, 2019) has satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, we are not proposing to apply a budget neutrality payment offset to payments to CAHs in FY 2022. This policy will have no impact for any national payment system for FY 2022.

3. Provisions of the Consolidated Appropriations Act of 2021 (Pub. L. 116–159)

As stated earlier, section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorized the Secretary to conduct the Frontier Community Health Integration Project (FCHIP) demonstration for a 3-year period. Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extends the FCHIP Demonstration by 5 years. Specifically, the Consolidated Appropriations Act amended subsection (f) of section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (42 U.S.C. 1395i–4 note) in paragraph (1), by striking ''3-year period beginning on October 1, 2009'' and inserting ''3-year period beginning on August 1, 2016 (referred to in this section as the ''initial period'' '), and 5-year period beginning on July 1, 2021 (referred to in this section as the ''extension period''). Thus, the FCHIP Demonstration will resume on July 1, 2021 and CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after July 1.

The Secretary is required to conduct the demonstration for an additional 5-year period. Only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, based on the data available, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. We will determine the budget neutrality approach for the FCHIP Demonstration extension period once data is available for the extension period.

VIII. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2022

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an

LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate. In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

4. Best Available Data

In section I.F of the preamble of this proposed rule, we discussed how claims data from the MedPAR files and cost report data from HCRIS are the primary sources of data used in IPPS and LTCH PPS ratesetting. (We use the term ''ratesetting'' to describe the methods and processes we follow in determining the annual LTCH PPS payment rates and factors.) We also state that our goal is to always use the best available data overall for ratesetting. Ordinarily, the best available claims data for the LTCH

PPS ratesetting is the MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking, because in general it is the most complete full fiscal year of claims data available at the time of development of the rule. Therefore, for FY 2022 ratesetting, under ordinary circumstances, the best available claims data would be the FY 2020 MedPAR file. Similarly, the best available cost report data for LTCH PPS ratesetting is ordinarily from the HCRIS dataset containing cost reports beginning 3 years prior to the fiscal year that is the subject of the rulemaking, because in general it is the most complete full fiscal year of cost report data available at the time of development of the rule. Therefore, for FY 2022 ratesetting, under ordinary circumstances, that would be the HCRIS dataset from FY 2019, which would primarily contain cost reports beginning during FY 2019 and ending during FY 2020, based on each LTCH's fiscal year. The FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset, however, both contain data significantly impacted by the COVID–19 PHE, meaning primarily the utilization of LTCH services was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. To determine whether these data are still the best available data for LTCH PPS ratesetting, it is important to evaluate whether these data would better approximate the FY 2022 LTCH experience than data from before the COVID–19 PHE.

In section I.F of the preamble of this proposed rule, we discuss our examination of COVID–19 vaccination data from the CDC to help evaluate whether the FY 2020 data we ordinarily would use in ratesetting is appropriate for approximating the FY 2022 inpatient experience, including in LTCHs. The CDC data shows that as of April 15, the 7-day average number of administered vaccine doses reported to CDC per day was 3.3 million, a 10.3 percent increase from the previous week. As of April 15, 80 percent of people 65 or older have received at least one dose of vaccine; 63.7 percent are fully vaccinated. Nearly one-half (48.3 percent) of people 18 or older have received at least one dose of vaccine; 30.3 percent are fully vaccinated. Nationally, COVID–19-related emergency department visits as well as both hospital admissions and current hospitalizations have risen among patients ages 18 to 64 years in recent weeks, but emergency department visits and hospitalizations among people ages 65 years and older have decreased, likely demonstrating the important role vaccination plays in protecting against COVID–19.

As indicated by the CDC, COVID–19 vaccines are effective at preventing COVID–19. For example, a recent CDC report on the effectiveness of the Pfizer-BioNTech and Moderna COVID–19 vaccines when administered in real-world conditions found that after being fully vaccinated with either of these vaccines a person's risk of infection is reduced by up to 90 percent. With respect to inpatient utilization in FY 2020, we believe that COVID–19 and the risk of disease were drivers of the different utilization patterns observed. Therefore, the continuing rapid increase in vaccinations coupled with the overall effectiveness of the vaccines leads us to conclude based on the information available to us at this time that there will be significantly lower risk of COVID–19 in FY 2022 and fewer hospitalizations for COVID–19 for Medicare beneficiaries in FY 2022 than there were in FY 2020. We concluded that this trend calls into question the applicability of inpatient hospital data from FY 2020 to the FY 2022 time period. We refer readers to section I.F of the preamble of this proposed rule for the details on this analysis.

In section I.F of the preamble of this proposed rule, we also discuss CDC guidance to healthcare facilities during the COVID–19 PHE (see *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html*). In its most recent guidance, the CDC described how the COVID–19 pandemic has changed how health care is delivered in the United States, and has affected the operations of healthcare facilities. Effects cited by the CDC include increases in patients seeking care for respiratory illnesses, patients deferring and delaying non-COVID–19 care, disruptions in supply chains, fluctuations in facilities' occupancy, absenteeism among staff because of illness or caregiving responsibilities, and increases in mental health concerns.

When comparing LTCH claims data from the FY 2020 MedPAR to the FY 2019 MedPAR, similar to the findings for IPPS claims data, we observed several of the changes cited by the CDC. Overall, in FY 2020 LTCH admissions of LTCH PPS standard Federal payment rate cases declined 13 percent compared to FY 2019. However, LTCH PPS standard Federal payment rate cases for MS–LTC–DRG 177 (Respiratory infections and inflammations with MCC), one of the MS–LTC–DRGs most often associated with the treatment of COVID–19, increased by 47 percent. Its share of total LTCH PPS standard Federal payment rate cases increased from 2.0 percent in FY 2019 to 3.4 percent in FY 2020. We also calculated and compared the aggregate case-mix values for LTCH PPS standard Federal payment rate cases in FY 2019 and FY 2020. For FY 2019 we calculated a case-mix value of 1.257 and for FY 2020 we calculated a case-mix value of 1.283, a relatively large 1-year increase in total case-mix of 2.1 percent. We note that these observed changes in the LTCH claims data also extend to the cost reports submitted by LTCHs that include the COVID–19 PHE time period, since those cost reports that extend into the COVID–19 PHE are based in part on the discharges that occurred during that time.

After analyzing this issue, we believe that the utilization patterns reflected in the FY 2020 LTCH claims data were significantly altered by the COVID–19 PHE. We also believe that data from before the COVID–19 PHE will better approximate the FY 2022 LTCH experience for the reasons discussed in section I.F of the preamble of this proposed rule, including an increase in the number of individuals who are vaccinated against COVID–19. Therefore, we are proposing to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE. For example, we are proposing to use the FY 2019 MedPAR claims data and the FY 2018 HCRIS file in situations where we ordinarily would have used the FY 2020 MedPAR and the FY 2019 HCRIS file, respectively. This proposal is consistent with the proposal made for FY 2022 IPPS ratesetting in section I.F of the preamble of this proposed rule, and we note that IPPS rates and factors are used in determining the IPPS comparable amount under the short-stay outlier (SSO) policy at § 412.529 and the IPPS comparable amount under the site neutral payment rate at § 412.522. We refer readers to section I.F of the preamble of this proposed rule for further information on this proposal.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2022

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the

requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. For FY 2022, there would be 767 MS–DRG groupings based on the proposed changes, as discussed in section II.E. of the preamble of this proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. Then we assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs. In this section of this proposed rule, we provide a general summary of our existing methodology for determining the FY 2022 MS–LTC–DRG relative weights under the LTCH PPS.

We are proposing in this FY 2022 IPPS/LTCH PPS proposed rule, in general, for FY 2022, to continue to use our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.B.3. of the preamble of this proposed rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, we are proposing that the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.B.3.c. of the preamble of this proposed rule). In addition, for FY 2022, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.B.3.c. of the preamble of this proposed rule.

Furthermore, for FY 2022, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we are proposing to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we grouped all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we accounted for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we made adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.B.3.g. of the preamble of this proposed rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as

MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim. Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2022

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2021 through September 30, 2022 (FY 2022), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2022 presented in section II.F. of the preamble of this proposed rule are the same as the MS–DRGs being proposed for use under the IPPS for FY 2022. In addition, because the proposed MS–LTC–DRGs for FY 2022 are the same as the proposed MS–DRGs for FY 2022, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 39 as discussed in section II.E. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also are applicable under the LTCH PPS for FY 2022.

3. Development of the Proposed FY 2022 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2022

In this proposed rule, we are proposing to continue to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2022, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our proposed application of our existing methodology for determining the proposed MS–LTC–DRG relative weights for FY 2022, and we discuss the effects of our proposals concerning the data used to determine the proposed FY 2022 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.We generally provide the low-volume quintiles and no-volume crosswalk data previously published in Tables 13A and 13B for each annual proposed and final rule as one of our supplemental IPPS/LTCH PPS related data files that are made available for public use via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of IPPS Table 11 and to make it easier for the public to navigate and find the relevant data and information used for the development of proposed and final payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years (83 FR 41522). We refer readers to the CMS website for the low-volume quintiles and no-volume crosswalk data previously furnished via Tables 13A and 13B.

c. Data

Ordinarily, for this FY 2022 proposed rule, we would use FY 2020 Medicare LTCH claims data for purposes of calculating the proposed MS–LTC–DRG relative weights for FY 2022. As discussed in section VII.A.4 of the preamble of this proposed rule, we believe the utilization patterns reflected in the FY 2020 LTCH claims data was significantly impacted by the COVID–19 PHE. Therefore, for the purposes of calculating the proposed MS–LTC–DRG relative weights for FY 2022, we are proposing to use FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 MedPAR file, which we believe are the best available data at this time for the reasons discussed in section VII.A.4 of the preamble of this proposed rule. Specifically, for this FY 2022 IPPS/LTCH PPS proposed rule, we obtained total charges from FY 2019 Medicare LTCH claims data from the March 2020 update of the FY 2019 MedPAR file and are proposing to use proposed Version 39 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing to use the best available data, if applicable, in the final rule. Specifically, we would use those data and the finalized Version 39 of the GROUPER in establishing the FY 2022 MS–LTC–DRG relative weights in the final rule.

To calculate the proposed FY 2022 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80

FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2020 update of the FY 2019 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2019 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2019 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that, for purposes of developing the MS–LTC–DRG relative weights we have previously addressed the treatment of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals or for certain severe wound care discharges from certain LTCHs provided by sections 15009 and 15010 of Public Law 114–255, respectively. The temporary exception from the site neutral payment rate for certain spinal cord specialty hospitals is effective for discharges in cost reporting periods beginning during FYs 2018 and 2019, and the temporary exception from the site neutral payment rate for certain severe wound care discharges from certain LTCHs was effective for a discharge in cost reporting period beginning during FY 2018. These statutory provisions will no longer be in effect for any discharges occurring in FY 2022. Therefore, consistent with our historical policy of only using cases that meet the criteria for exclusion from the site neutral payment rate, we excluded these cases in our development of the proposed MS–LTC–DRG relative weights for FY 2022.)

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the MS–LTC–DRG relative weights for FY 2021.

In summary, in general, we identified the claims data used in the development of the proposed FY 2022 MS–LTC–DRG relative weights in this proposed rule by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the dual payment rate structure been in effect. Finally, we propose to trim the claims data of all-inclusive rate providers reported in the March 2020 update of the FY 2019 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2020 update of the FY 2019 MedPAR file, but, had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy. We are proposing to use the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2022.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2022. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2022, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. (Step 3) of the preamble of this proposed rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§§ 412.529 and 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative

charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of this proposed rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail in this proposed rule). For FY 2022, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the proposed FY 2022 MS–LTC–DRG relative weights.

In determining the proposed FY 2022 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.B.3.g. of the preamble of this proposed rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148).) In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, we propose to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.B.3.g. (Step 6) of the preamble of this proposed rule.

In this proposed rule, based on the best available data (that is, the March 2020 update of the FY 2019 MedPAR files), we identified 251 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles, each containing at least 50 MS–LTC–DRGs (251/5 = 50 with a remainder of 1). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, we are proposing to employ our historical methodology for determining which of the low-volume quintiles would contain the additional low-volume MS–LTC–DRG. Specifically for this proposed rule, because the average charge of the 51st low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 50th low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 52nd low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 51 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed in this proposed rule). This resulted in 4 of the 5 low-volume quintiles containing 50 MS–LTC–DRGs (Quintiles 2, 3, 4, and 5) and 1 of the low-volume quintiles containing 51 MS–LTC–DRGs (Quintile 1). As discussed earlier, for this proposed rule, we are providing the list of the composition of the proposed low-volume quintiles for proposed low-volume MS–LTC–DRGs for FY 2022 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

In order to determine the proposed FY 2022 relative weights for the proposed low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the methodology described in section VII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2022 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2022 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2022 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described previously) and cross-walked proposed no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we are proposing to calculate the proposed FY 2022 relative weights by first removing cases with a length of stay of

7 days or less and statistical outliers (Steps 1 and 2). Next, we are proposing to adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1) and statistical outliers (Step 2), which are the SSO-adjusted applicable LTCH cases and corresponding charges (Step 3), we are proposing to calculate proposed ''relative adjusted weights'' for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our proposed calculation of the proposed FY 2022 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2022 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2022 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our proposed calculation of the proposed FY 2022 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the proposed relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the proposed FY 2022 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2022 MS–LTC–DRG relative weights would lower the proposed FY 2022 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are proposing to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2022 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2022 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we calculated the proposed FY 2022 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the proposed MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 3 for each proposed MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 3 for each proposed MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2022 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the proposed MS–LTC–DRGs for which there were no claims in the March 2020 update of the FY 2019 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, we are proposing to crosswalk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a proposed relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' proposed MS–LTC–DRG is assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this proposed rule).

Of the 767 proposed MS–LTC–DRGs for FY 2022, we identified 375 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. This number includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 347 MS–LTC–DRGs that for which we would propose to assign a relative weight using our existing ''no-volume'' proposed MS–LTC–DRG methodology (that is, $375 - 11 - 2 - 15 = 347$). We are proposing to assign proposed relative weights to each of the 347 no-volume proposed MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 392 ($767 - 375 = 392$) proposed MS–LTC–DRGs for which we calculated proposed relative weights based on the trimmed applicable LTCH cases in the FY 2019 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' proposed MS–LTC–DRGs as one of the 392 proposed MS–LTC–DRGs to which we cross-walked each of the 347 ''no-volume'' proposed MS–LTC–DRGs.) Then, we are generally proposing to assign the 347 no-volume proposed MS–LTC–DRGs the proposed relative weight of the cross-walked proposed MS–LTC–DRG. (As explained in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we calculated proposed relative weights based on the March 2020 update of the FY 2019 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume proposed MS–LTC–DRGs in FY 2022, the proposed relative weights assigned based on the cross-walked proposed MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the proposed relative weight of the cross-walked proposed MS–LTC–DRG as the proposed relative weight for the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight (and average length of stay) for FY 2022. We note that, if the cross-walked proposed MS–LTC–DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume proposed MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume proposed MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight for FY 2022. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume proposed MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing proposed relative weights.)

As discussed earlier, for this proposed rule, we are providing the list of the no-volume proposed MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked proposed MS–LTC–DRGs) for FY 2022 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this proposed methodology for determining the proposed relative weights for the proposed FY 2022 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS–LTC–DRGs crosswalk information for FY 2022 (which, as previously stated, we are providing in a supplemental data file posted via the internet on the CMS website for this proposed rule).

Example: There were no trimmed applicable LTCH cases in the FY 2019 MedPAR file that we are using for this proposed rule for MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that MS–LTC–DRG 070 (Nonspecific cerebrovascular disorders with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we are proposing to assign the same relative weight (and average length of stay) of MS–LTC–DRG 70 of 0.8730 for FY 2022 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice,

we are proposing to use the best available claims data, if applicable, to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2022, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are proposing to establish a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We propose to establish a relative weight 0.0000 for these 15 ''psychiatric or rehabilitation'' MS LTC DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate will not be applicable for any LTCH discharges occurring in FY 2022, and as such payment under the LTCH PPS will be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–DRGs.

Step 6—Adjust the proposed FY 2022 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2022 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2022 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

Step 7—Calculate the proposed FY 2022 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the

annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the best available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2022 based on the best available LTCH data for applicable LTCH cases, and continue to apply a budget neutrality adjustment in determining the FY 2022 MS–LTC–DRG relative weights.

In this proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology.

To calculate the proposed normalization factor for FY 2022, we are proposing to group applicable LTCH cases using the proposed FY 2022 Version 39 GROUPER, and the recalibrated proposed FY 2022 MS–LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2021 GROUPER Version 38 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2021 by the average CMI for proposed FY 2022. That ratio is the proposed normalization factor. Because the calculation of the proposed normalization factor involves the proposed relative weights for the proposed MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume proposed MS–LTC–DRGs are included in the calculation (and the proposed MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the proposed budget neutrality adjustment factor, we simulated estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed FY 2022 normalized relative weights and proposed GROUPER Version 39; simulated estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2021 MS–LTC–DRG relative weights and the FY 2021 GROUPER Version 38; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2021 MS–LTC–DRG relative weights and the GROUPER Version 38 by the simulated estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2022 MS–LTC–DRG relative weights and the proposed GROUPER Version 39. The resulting ratio is the proposed budget neutrality adjustment factor. The calculation of the proposed budget neutrality factor involves the proposed relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume proposed MS–LTC–DRGs, and generally does not include payments for cases grouped to a proposed MS–LTC–DRG with no applicable LTCH cases. Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less), which are removed from the proposed relative weight calculation in step 2 that are grouped to a proposed MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the proposed budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the proposed budget neutrality factor calculation).

In this proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in this proposed rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2022, we are proposing to calculate and apply a proposed normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the proposed changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2022 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2019 MedPAR file) and group them using the proposed FY 2022 GROUPER (that is, proposed Version 39 for FY 2022) and the recalibrated proposed FY 2022 MS–LTC–DRG relative weights (determined in Steps 1 through 6 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2021 GROUPER (Version 38) and FY 2021 MS–LTC–DRG relative weights and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2021 (determined in Step 1.b.) by the average case-mix index for FY 2022 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2022, each recalibrated proposed MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.25811 (determined in Step 1.c.) in the first step of the proposed budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculated a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.b. stated previously) before reclassification and recalibration to estimated aggregate payments for FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration (that is, the sum of all calculations under Step 1.a. stated previously).

That is, for this proposed rule, for FY 2022, under the second step of the budget neutrality methodology, we are proposing to determine the proposed budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed normalized relative weights for FY 2022 and proposed GROUPER Version 39 (as described previously); (2.b.) simulate estimated total FY 2022 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2021 GROUPER (Version 38) and the FY 2021 MS–LTC–DRG relative weights in Table 11 of the FY 2021 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.)

calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2022 MS–LTC–DRG relative weights, each proposed normalized relative weight is then multiplied by a budget neutrality factor of 1.000275 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2022 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.25811 and a budget neutrality factor of 1.000275. Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2022.

C. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2022

1. Overview of Development of the Proposed LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2022, that is, effective for LTCH discharges occurring on or after October 1, 2021 through September 30, 2022. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2022 IPPS/LTCH PPS proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2022.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2022 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2022 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2022 as required by the statute (as discussed in section VII.C.2.c. of the preamble of this proposed rule). We are also proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2022 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule). (We note that we are not making any proposals which would change the proposed FY 2022 LTCH PPS standard Federal payment rate that are based on the elimination of the 25-percent threshold policy because the permanent, one-time factor was proposed and adopted in the FY 2021 IPPS/LTCH PPS Final Rule for FY 2021 and subsequent years (85 FR 58907)).

2. Proposed FY 2022 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2022

CMS has used an estimated market basket increase to update the LTCH PPS. As previously noted, we adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. (For additional details on the development of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In the FY 2021 IPPS/LTCH final rule, we finalized the price proxies for the 2017-based LTCH market basket. In that final rule, we established the use of the Moody's AAA Corporate Bond Yield index as the price proxy for the For-profit Interest cost category (85 FR 58919). Effective for December 2020, the

Moody's AAA Corporate Bond series is no longer available for use under license to IGI, the nationally-recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity adjustment (MFP). In this proposed rule, we are proposing to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index. We compared the iBoxx AAA Corporate Bond Yield index with the Moody's AAA Corporate Bond Yield index and found that the average growth rates in the history of the two series are very similar. Over the historical time period of FY 2001 to FY 2020, the 4-quarter percent change moving average growth in the iBoxx series was approximately 0.1 percentage point higher, on average, than the Moody's series. However, given the relatively small weight for this cost category, replacing the Moody's series with the iBoxx series does not impact the historical top-line market basket increases when rounded to the nearest tenth of a percentage point over the past ten fiscal years (FY 2011 to FY 2020). Therefore, because the iBoxx AAA Corporate Bond Yield index captures the same technical concept as the current corporate bond proxy and tracks similarly to the current measure that is no longer available, we believe that using the iBoxx AAA Corporate Bond Yield index is technically appropriate to use in the 2017-based LTCH market basket.

We continue to believe that the 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2021 IPPS/LTCH PPS final rule. Therefore, in this proposed rule, we are proposing to use the 2017-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2022.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the multifactor productivity (MFP) adjustment''). Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2022.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2022

Consistent with our historical practice, we estimate the market basket increase and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2020 forecast, the FY 2022 full market basket estimate for the LTCH PPS using the 2017-based LTCH market basket is 2.4 percent. The current estimate of the MFP adjustment for FY 2022 based on IGI's fourth quarter 2020 forecast is 0.2 percent.

For FY 2022, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, that is, the MFP adjustment as previously noted, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full estimated FY 2022 market basket increase by the FY 2022 MFP adjustment. To determine the proposed market basket increase for LTCHs for FY 2022, as reduced by the proposed MFP adjustment, consistent with our established methodology, we are subtracting the proposed FY 2022 MFP adjustment from the estimated FY 2022 market basket increase. (For additional details on our established methodology for adjusting the market basket increase by the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2022, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 2.4 percent update to the LTCH PPS standard Federal payment rate for FY 2022 would be reduced by the 0.2 percentage point MFP adjustment as required under section 1886(m)(3)(A)(i) of the Act and the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In this FY 2022 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2022 full market basket estimate of 2.4 percent (based on IGI's fourth quarter 2020 forecast of the 2017-based LTCH market basket) by the proposed FY 2022 MFP adjustment of 0.2 percentage point (based on IGI's fourth quarter 2020 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2022 of 2.2

percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.4 percent less the MFP adjustment of 0.2 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.2 percent (that is, 2.2 percent minus 2.0 percentage points) for FY 2022 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we are proposing to use a more recent estimate of the market basket and the MFP adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2022. (We note that, consistent with historical practice, we are also proposing to adjust the FY 2022 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the preamble of this proposed rule, we are seeking public comment on two focus areas, and are also proposing changes to the Medicare quality reporting systems:

- In section IX.A., advancing to digital quality measurement and the use of Fast Healthcare Interoperability Resources (FHIR) in hospital quality programs;
- In section IX.B., closing the health equity gap in CMS hospital quality programs;
- In section IX.C., the Hospital IQR Program;
- In section IX.D., the PCHQR Program; and
- In section IX.E., the LTCH QRP.

In addition, in section IX.F. of the preamble of this proposed rule, we are proposing changes to the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and critical access hospitals (CAHs).

A. Advancing to Digital Quality Measurement and the Use of Fast Healthcare Interoperability Resources (FHIR) in Hospital Quality Programs—Request for Information

We aim to move fully to digital quality measurement in CMS quality reporting and value-based purchasing programs by 2025. As part of this modernization of our quality measurement enterprise, we are issuing this request for information (RFI). The purpose of this RFI is to gather broad public input solely for planning purposes for our transition to digital quality measurement. Any updates to specific program requirements related to providing data for quality measurement and reporting provisions would be addressed through future rulemaking, as necessary. This RFI contains five parts:

- Background. This part provides information on our quality measurement programs and our goal to move fully to digital quality measurement by 2025. This part also provides a summary of recent HHS policy developments that are advancing interoperability and could support our move towards full digital quality measurement.
- Definition of Digital Quality Measures (dQMs). This part provides a potential definition for dQMs. Specific requests for input are included in the section.
- Use of Fast Healthcare Interoperability Resources (FHIR®) for current electronic clinical quality measures (eCQMs). This part provides information on current activities underway to align CMS eCQMs with the FHIR standard and support quality measurement via application programming interfaces (APIs), and contrasts this approach to current eCQM standards and practice.
- Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025. This part introduces four possible steps that would enable transformation of CMS' quality measurement enterprise to be fully digital by 2025. Specific requests for input are included in the section.
- Solicitation of Comments. This part lists all requests for input included in the sections of this RFI.

1. Background

As required by law, we implement quality measurement and value-based purchasing programs across a broad range of inpatient acute care, outpatient, and post-acute care (PAC) settings consistent with our mission to improve the quality of health care for Americans through measurement, transparency, and increasingly, value-based purchasing. These quality programs are foundational for incentivizing value-based care, contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework for quality measurement captures our vision to better address health care quality priorities and gaps, including emphasizing digital quality measurement, reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework evolves as the health care environment continues to change.[966] Consistent with the Meaningful Measures Framework, we aim to move fully to digital quality measurement by 2025. We acknowledge providers within the various care and practice settings covered by our quality programs may be at different stages of readiness, and therefore, the timeline for achieving full digital quality measurement across our quality reporting programs may vary.

We also continue to evolve the Medicare Promoting Interoperability Program's focus on the use of certified electronic health record (EHR) technology, from an initial focus on electronic data capture to enhancing information exchange and expanding quality measurement (83 FR 41634). However, reporting data for quality measurement via EHRs remains burdensome, and our current approach to quality measurement does not readily incorporate emerging data sources such as patient-reported outcomes (PRO) and patient-generated health data (PGHD).[967] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

Additionally, advancements in technical standards and associated regulatory initiatives to improve interoperability of healthcare data are creating an opportunity to significantly improve our quality measurement systems. In May 2020, we finalized interoperability requirements in the CMS Interoperability and Patient Access final rule (85 FR 25510) to support beneficiary access to data held by

[966] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[967] What are patient generated health data: *https://www.healthit.gov/topic/otherhot-topics/what-are-patient-generated-health-data.*

certain payers. At the same time, the Office of the National Coordinator for Health Information Technology (ONC) finalized policies in the ONC 21st Century Cures Act final rule (85 FR 25642) to advance the interoperability of health information technology (IT) as defined in section 4003 of the Cures Act, including the ''complete access, exchange, and use of all electronically accessible health information.'' Closely working with ONC, we collaboratively identified Health Level 7 (HL7®) FHIR Release 4.0.1 as the standard to support Application Programming Interface (API) policies in both rules. ONC, on behalf of HHS, adopted the HL7 FHIR Release 4.0.1 for APIs and related implementation specifications at 45 CFR 170.215. We believe the FHIR standard has the potential to be a more efficient and modular standard to enable APIs. We also believe this standard enables collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost. By aligning technology requirements for payers, health care providers, and health IT developers HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

In the ONC 21st Century Cures Act final rule, ONC adopted a ''Standardized API for Patient and Population Services'' certification criterion for health IT that requires the use of FHIR Release 4 and several implementation specifications. Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications (85 FR 25742).[968] The ONC 21st Century Cures Act final rule also requires health IT developers to update their certified health IT to support the United States Core Data for Interoperability (USCDI) standard.[969] The scope of patient data identified in the USCDI and the data standards that support this data set are expected to evolve over time, starting with data specified in Version 1 of the USCDI. In November 2020, ONC issued an interim final rule with comment period extending the date when health IT developers must make technology meeting updated certification criteria available under the ONC Health IT Certification Program until December 31, 2022 (85 FR 70064).[970]

The CMS Interoperability and Patient Access final rule (85 FR 25510) and program policies build on the ONC 21st Century Cures Act final rule (85 FR 25642). The CMS Interoperability and Patient Access final rule and policies require certain payers (for example, Medicare Advantage organizations, Medicaid and CHIP Fee-for-Service programs, Medicaid managed care plans, CHIP managed care entities, and issuers of certain Qualified Health Plan [QHP] on the Federally-facilitated Exchanges [FFEs]) to implement and maintain a standards-based Patient Access API using HL7 FHIR Release 4.0.1 to make available certain data to their enrollees and beneficiaries (called ''patients'' in the CMS interoperability rule). These certain data include data concerning claims and encounters, with the intent to ensure access to their own health care information through third-party software applications. The rule also established new Conditions of Participation for Medicare and Medicaid participating hospitals and critical access hospitals (CAHs), requiring them to send electronic notifications to another healthcare facility or community provider or practitioner when a patient is admitted, discharged, or transferred (85 FR 25603). In the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84472), we finalized a policy to align the certified EHR technology required for use in the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category with the updates to health IT certification criteria finalized in the ONC 21st Century Cures Act final rule. Under this policy, MIPS eligible clinicians, and eligible hospitals and CAHs participating in the Promoting Interoperability Programs, must use technology meeting the updated certification criteria for performance and reporting periods beginning in 2023 (85 FR 84825).

The use of APIs can also reduce long-standing barriers to quality measurement. Currently, health IT developers are required to implement individual measure specifications within their health IT products. The health IT developer must also accommodate how that product connects with the unique variety of systems within a specific care setting.[971] This may be further complicated by systems that integrate a wide range of data schemas. This process is burdensome and costly, and it is difficult to reliably obtain high quality data across systems. As health IT developers map their health IT data to the FHIR standard and related implementation specifications, APIs can enable these structured data to be easily accessible for quality measurement or other use cases, such as care coordination, clinical decision support, and supporting patient access.

We believe the emerging data standardization and interoperability enabled by APIs will support the transition to full digital quality measurement by 2025, and are committed to exploring and seeking input on potential solutions for the transition to digital quality measurement as described in this RFI.

2. Definition of Digital Quality Measures

In this section we seek to refine the definition of digital quality measures (dQMs) to further operationalize our objective of fully transitioning to dQMs by 2025. We previously noted dQMs use ''sources of health information that are captured and can be transmitted electronically and via interoperable systems.'' (85 FR 84845) In this RFI, we seek input on future elaboration that would define a dQM as a software that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. We also note that dQMs are intended to improve the patient experience including quality of care, improve the health of populations, and/or reduce costs.

We discuss one potential approach to developing dQM software in section IX.A.4.b. of the preamble of this proposed rule. In this section, we are seeking comment on the potential definition of dQMs in this RFI.

We also seek feedback on how leveraging advances in technology (for

[968] Application Programming Interfaces (API) Resource Guide, Version 1.0. Available at: *https://www.healthit.gov/sites/default/files/page/2020-11/API-Resource-Guide_v1_0.pdf.*

[969] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[970] Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the Covid-19 Public Health Emergency. Available at: *https://www.govinfo.gov/content/pkg/FR-2020-11-04/pdf/2020-24376.pdf.*

[971] The Office of the National Coordinator for Health Information Technology, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, Final Report (Feb. 2020). Available at: *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

example, FHIR APIs) to access and electronically transmit interoperable data for dQMs could reinforce other activities to support quality measurement and improvement (for example, the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements).

The transition to dQMs relies on advances in data standardization and interoperability. As providers and payers work to implement the required advances in interoperability over the next several years, we will continue to support reporting of eCQMs through CMS quality reporting programs and through the Promoting Interoperability programs.[972] These fully digital measures continue to be important drivers of interoperability advancement and learning. As discussed in the next section, CMS is currently re-specifying and testing these measures to use FHIR rather than the currently adopted Quality Data Model (QDM) in anticipation of the wider use of FHIR standards. CMS intends to apply significant components of the output of this work, such as the re-specified measure logic and the learning done through measure testing with FHIR APIs, to define and build future dQMs that take advantage of the expansion of standardized, interoperable data.

3. Use of FHIR for Current eCQMs

Since we adopted eCQMs in our hospital and clinician quality programs, we have heard from stakeholders about the technological challenges, burden, and related costs of reporting eCQM data. The CMS eCQM Strategy Project engaged with stakeholders through site visits and listening sessions with health systems and provider organizations to learn about their experiences. This stakeholder feedback identified recommendations to improve processes related to alignment; development; implementation and reporting; certification; and communication, education, and outreach. Over the past two years, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring FHIR® (*http://hl7.org/fhir*) as a framework for measure structure and data submission for quality reporting programs, specifically for eCQMs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health information technology. FHIR allows systems to communicate and information to be shared seamlessly, with a lower burden for hospitals, providers, clinicians, vendors, and quality measurement stakeholders. Specifically, for quality reporting, FHIR enables representing the data in eCQMs as well as provides a structure for eCQMs and reporting, using FHIR as the standard for all. Whereas today, multiple standards being used to report eCQMs is challenging and burdensome.

We are working to convert current eCQMs to the FHIR standard. We are currently testing the exchange of data elements represented in FHIR to CMS through ongoing HL7 Connectathons and integrated system testing by using and refining implementation guides. Submitting data through FHIR APIs has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users. In addition, development of FHIR APIs could decrease provider burden by automating more of the measure data collection process. We continue to explore and expand potential applications of the FHIR standard and testing with eCQM use cases, and we are strongly considering a transition to FHIR-based quality reporting with the use of the FHIR standard for eCQMs in quality and value-based reporting programs. As we move to an all-dQM format for quality programs, we are depending on testing results and community readiness to improve interoperability, reduce burden, and facilitate better patient care. We will continue to consider how to leverage the interoperability advantages offered by the FHIR standards and API-based data submission, including digital quality measurement.

4. Changes Under Consideration To Advance Digital Quality Measurement: Potential Actions in Four Areas To Transition to Digital Quality Measures by 2025

Building on the advances in interoperability and learning from testing of FHIR-converted eCQMs, we aim to move fully to dQMs, originating from sources of health information that are captured and can be transmitted electronically via interoperable systems, by 2025.

To enable this transformation, we are considering further modernization of the quality measurement enterprise in four major ways: (1) Leverage and advance standards for digital data and obtain all EHR data required for quality measures via provider FHIR-based APIs; (2) redesign our quality measures to be self-contained tools; (3) better support data aggregation; and (4) work to align measure requirements across our reporting programs, other Federal programs and agencies, and the private sector where appropriate.

These changes would enable us to collect and utilize more timely, actionable, and standardized data from diverse sources and care settings to improve the scope and quality of data used in quality reporting and payment programs, reduce quality reporting burden, and make results available to stakeholders in a rapid-cycle fashion. Data collection and reporting efforts would become more efficient, supported by advances in interoperability and data standardization. Aggregation of data from multiple sources would allow assessments of costs and outcomes to be measured across multiple care settings for an individual patient or clinical conditions. We believe that aggregating data for measurement can incorporate a more holistic assessment of an individual's health and health care and produce the rich set of data needed to enable patients and caregivers to make informed decisions by combining data from multiple sources (for example, patient reported data, EHR data, and claims data) for measurement.

Perhaps most importantly, these steps would help us deliver on the full promise of quality measurement and drive us toward a learning health system that transforms healthcare quality, safety, and coordination and effectively measures and achieves value-based care. The shift from a static to a learning health system hinges on the interoperability of healthcare data, and the use of standardized data. dQMs would leverage this interoperability to deliver on the promise of a learning health system wherein standards-based data sharing and analysis, rapid-cycle feedback, and quality measurement and incentives are aligned for continuous improvement in patient-centered care. Similarly, standardized, interoperable data used for measurement can also be used for other use cases, such as clinical decision support, care coordination and care decision support, which impacts health care and care quality.

We are requesting comments on four potential future actions that would enable transformation to a fully digital quality measurement enterprise by 2025.

a. Leveraging and Advancing Standards for Digital Data and Obtaining All EHR Data Required for Quality Measures via Provider FHIR-based APIs

We are considering targeting the data required for our quality measures that

[972] eCQI Resource Center, *https://ecqi.healthit.gov/*.

utilize EHR data to be data retrieved via FHIR-based APIs based on standardized, interoperable data. Utilizing standardized data for EHR-based measurement (based on FHIR and associated implementation guides) and aligning where possible with interoperability requirements can eliminate the data collection burden providers currently experience with required chart-abstracted quality measures and reduce the burden of reporting digital quality measure results. We can fully leverage this advance to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources. We are considering methods and approaches to leverage the interoperability data requirements for APIs in certified health IT set by the ONC 21st Century Cures Act final rule to support modernization of CMS quality measure reporting. As discussed previously, these requirements will be included in certified technology in future years (85 FR 84825) including availability of data included in the USCDI via standards-based APIs, and CMS will require clinicians and hospitals participating in MIPS and the Promoting Interoperability Programs, respectively, to transition to use of certified technology updated consistent with the 2015 Cures Edition Update (85 FR 84825).

Digital data used for measurement could also expand beyond data captured in traditional clinical settings, administrative claims data, and EHRs. Many important data sources are not currently captured digitally, such as survey and PGHD. We intend to work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and administrative claims. Agreed upon standards for these data, and associated implementation guides will be important for interoperability and quality measurement. We will consider developing clear guidelines and requirements for these digital data that align with interoperability requirements, for example, requirements for expressing data in standards, exposing data via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability.

High quality data are also essential for reliable and valid measurement. Hence, in implementing the shift to collect all clinical EHR data via FHIR-based APIs, we would support efforts to strengthen and test the quality of the data obtained through FHIR-based APIs for quality measurement. We currently conduct audits of electronic data submitted to the Hospital IQR Program with functions including checks for data completeness and data accuracy, confirmation of proper data formatting, alignment with standards, and appropriate data cleaning (82 FR 38398 through 38402). These functions would continue and be applied to dQMs and further expanded to automate the manual validation of the data compared to the original data source (for example, the medical record) where possible. Analytic advancements such as natural language processing, big data analytics, and artificial intelligence, can support this evolution. These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations, as data are received, to ensure high quality data are used for measurement.

We are seeking feedback on the goal of aligning data needed for quality measurement with interoperability requirements and the strengths and limitations of this approach. We are also seeking feedback on the importance of and approaches to supporting inclusion of PGHD and other currently non-standardized data. We also welcome comment on approaches for testing data quality and validity.

b. Redesigning Quality Measures To Be Self-Contained Tools

We are considering approaches for including quality measures that take advantage of standardized data and interoperability requirements that have expanded flexibility and functionality compared to CMS' current eCQMs. We are considering defining and developing dQM software as end-to-end measure calculation solutions that retrieve data from primarily FHIR-based resources maintained by providers, payers, CMS, and others; calculate measure score(s), and produce reports. In general, we believe to optimize the use of standardized and interoperable data, the software solution for dQMs should do the following:

- Have the flexibility to support calculation of single or multiple quality measure(s).
- Perform three functions—

++ Obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in the future from claims, PRO, and PGHD);

++ Calculate the measure score according to measure logic; and

++ Generate measure score report(s).

- Be compatible with any data source systems that implement standard interoperability requirements.
- Exist separately from digital data source(s) and respect the limitations of the functionality of those data sources.
- Be tested and updated independently of the data source systems.
- Operate in accordance with health information protection requirements under applicable laws and comply with governance functions for health information exchange.
- Have the flexibility to be deployed by individual health systems, health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications.
- Be designed to enable easy installation for supplemental uses by medical professionals and other non-technical end-users, such as local calculation of quality measure scores or quality improvement.
- Have the flexibility to employ current and evolving advanced analytic approaches such as natural language processing.
- Be designed to support pro-competitive practices for development, maintenance, and implementation as well as diffusion of quality measurement and related quality improvement and clinical tools through, for example, the use of open-source core architecture.

We seek comment on these suggested functionalities and other additional functionalities that quality measure tools should ideally have particularly in the context of the possible expanding availability of standardized and interoperable data (for example, standardized EHR data available via FHIR-based APIs).

We are also interested whether and how this more open, agile strategy may facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research.

c. Building a Pathway to Data Aggregation in Support of Quality Measurement

Using multiple sources of collected data to inform measurement would reduce data fragmentation (or, different pieces of data regarding a single patient stored in many different places). Additionally, we are considering expanding and establishing policies and processes for data aggregation and measure calculation by third-party aggregators that include, but are not limited to, HIEs and clinical registries. Qualified Clinical Data Registries and Qualified Registries that report quality measures for eligible clinicians in the Merit-based Incentive Payment System

(MIPS) program are potential examples [973] at 42 CFR 414.1440(b)(2)(iv) and (v) and 414.1440(c)(2)(iii) and (iv) and can also support measure reporting. We are considering establishing similar policies for third-party aggregators to maintain the integrity of our measure reporting process and to encourage market innovation.

We seek feedback on aggregation of data from multiple sources to inform measurement and potential policy considerations. We also seek feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers, and how we can best facilitate and enable aggregation.

d. Potential Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to solve the issue of interoperable data exchange and to transition to full digital quality measurement. We are considering the future potential development and multi-staged implementation of a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measure logic. Further, the required data elements would be limited to standardized, interoperable data elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and State agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and State agencies and payers to the extent possible.

We intend for this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, disparities, and care coordination), and track with the transformation of data collection, alignment with health IT module updates including capabilities and standards adopted by ONC (for example, standards to enable APIs). This coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[974] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (Department of Defense and Veterans Affairs [DoD/VA]); the Agency for Healthcare Research and Quality's Clinical Decision Support Initiative; the Centers for Disease Control and Prevention's Adapting Clinical Guidelines for the Digital Age initiative; Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, National Quality Forum (NQF), provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, State, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements for measures as well as the requirements of other agencies and payers.

We seek feedback on initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools, and data standards). We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities across sectors.

5. Solicitation of Comments

As noted previously, we seek input on the future development of the following:

- Definition of Digital Quality Measures. We are seeking feedback on the following as described in section IX.A.2. of the preamble of this proposed rule:

++ Do you have feedback on the dQM definition?

++ Does this approach to defining and deploying dQMs to interface with FHIR-based APIs seem promising? We also welcome more specific comments on the attributes or functions to support such an approach of deploying dQMs.

- Use of FHIR for Current eCQMs. We are seeking feedback on the following as described in section IX.A.3. of the preamble of this proposed rule:

++ Do you agree that a transition to FHIR-based quality reporting can reduce burden on health IT vendors and providers?

++ Would access to near real-time quality measure scores benefit your practice?

++ What parts of the current CMS QRDA IGs cause the most burden?

++ What could we include in a CMS FHIR Reporting IG to reduce burden on providers and vendors?

- Changes Under Consideration to Advance Digital Quality Measurement: Actions in Four Areas to Transition to Digital Quality Measures by 2025.

++ We are seeking feedback on the following as described in section IX.A.4.a. of the preamble of this proposed rule:

— Do you agree with the goal of aligning data needed for quality measurement with interoperability requirements? What are the strengths and limitations of this approach? Are there specific FHIR Implementation Guides suggested for consideration?

— How important is a data standardization approach that also supports inclusion of PGHD and other currently non-standardized data?

— What are possible approaches for testing data quality and validity?

++ We are seeking feedback on the following as described in section IX.A.4.b. of the preamble of this proposed rule:

— What functionalities, described in Section (4)(b) or others, should quality measure tools ideally have in the context of the pending availability of standardized and interoperable data (for

[973] Calendar Year (CY) 2021 Physician Fee Schedule Final Rule: Finalized (New and Updated) Qualified Clinical Data Registry (QCDR) and Qualified Registry Policies, *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1362/QCDR%20and%20QR%20Updates%202021%20Final%20Rule%20Fact%20Sheet.pdf.*

[974] Department of Health and Human Services, National Health Quality Roadmap (May 2020). Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

example, standardized EHR data available via FHIR-based APIs)?

— How would this more open, agile strategy for end-to-end measure calculation facilitate broader engagement in quality measure development, the use of tools developed for measurement for local quality improvement, and/or the application of quality tools for related purposes such as public health or research?

++ We seek feedback on the following as described in section IX.A.4.c. of the preamble of this proposed rule:

— Do you have feedback on policy considerations for aggregation of data from multiple sources being used to inform measurement?

— Do you have feedback on the role data aggregators can and should play in CMS quality measure reporting in collaboration with providers? How can CMS best facilitate and enable aggregation?

++ We seek feedback on the following as described in section IX.A.4.d. of the preamble of this proposed rule:

— What are initial priority areas for the dQM portfolio given evolving interoperability requirements (for example, measurement areas, measure requirements, tools)?

— We also seek to identify opportunities to collaborate with other Federal agencies, states, and the private sector to adopt standards and technology-driven solutions to address our quality measurement priorities and across sectors.

Commenters should consider provisions in the CMS Interoperability and Patient Access final rule (85 FR 25510), CMS CY 2021 PFS final rule (85 FR 84472), and the ONC 21st Century Cures Act final rule (85 FR 25642).

We plan to continue working with other agencies and stakeholders to coordinate and to inform any potential transition to dQMs by 2025. While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2022 IPPS/LTCH PPS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

B. Closing the Health Equity Gap in CMS Hospital Quality Programs—Request for Information

Persistent inequities in health care outcomes exist in the United States, including among Medicare patients. In recognition of persistent health disparities and the importance of closing the health equity gap, we request information on revising several related CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for hospitals, providers, and patients. The following is part of an ongoing effort across CMS to evaluate appropriate initiatives to reduce health disparities. Feedback will be used to inform the creation of a future, comprehensive, RFI focused on closing the health equity gap in CMS programs and policies. This RFI contains four parts:

- *Background.* This section provides information describing our commitment to health equity, and existing initiatives with an emphasis on reducing health disparities.
- *Current CMS Disparity Methods.* This section describes the methods, measures, and indicators of social risk currently used with the CMS Disparity Methods.
- *Future potential stratification of quality measure results by race and ethnicity.* This section describes three potential future expansions of the CMS Disparity Methods, including (a) Future potential stratification of quality measure results by race and ethnicity, (b) Improving Demographic Data Collection, and (c) Potential Creation of a Hospital Equity Score to Synthesize Results Across Multiple Social Risk Factors.
- *Solicitation of public comment.* This section specifies 10 requests for feedback on the topics listed previously. We look forward to receiving feedback on these topics and note for readers that responses to the RFI will not directly impact payment decisions. We also note our intention for an additional RFI or rulemaking on this topic in the future.

1. Background

Significant and persistent inequities in health care outcomes exist in the United States. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area; or being near or below the poverty level, is often associated with worse health outcomes.[975] [976] [977] [978] [979] [980] [981] [982] Such disparities in health outcomes are the result of number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[983] [984] [985] [986] [987] [988] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for Black

[975] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[976] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[977] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[978] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[979] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[980] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[981] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[982] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[983] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[984] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[985] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec; 73(12):2107–15.

[986] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[987] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[988] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[989] [990] [991] [992] [993] Studies have also shown that African Americans are significantly more likely than White Americans to die prematurely from heart disease and stroke.[994] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to White persons.[995] [996] As noted by the Centers for Disease Control ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19.'' [997] One important strategy for addressing these important inequities is improving data collection to allow for better measurement and reporting on equity across our programs and policies.

We are committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[998] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, issued on January 25, 2021, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [999] We note that this definition was recently established and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Network Quality Improvement Organizations (QIN–QIOs); Federal, State, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity.[1000] The CMS Equity Plan for Improving Quality in Medicare focuses on three core priority areas which inform our policies and programs: (1) Increasing understanding and awareness of health disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[1001] The CMS Quality Strategy [1002] and Meaningful Measures Framework [1003] also include elimination of racial and ethnic disparities as central principles. Our efforts aimed at closing the health equity gap to date have included providing transparency of health disparities, supporting providers and health officials with evidence-informed solutions to address social determinants of health and achieve health equity, and reporting to providers on gaps in quality as follows:

- The *CMS Mapping Medicare Disparities Tool* which is an interactive map that identifies areas of disparities and is a starting point to understand and investigate geographic, racial and ethnic differences in health outcomes for Medicare patients.[1004]
- The *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage Stratified Report,* which highlights racial and ethnic differences in health care experiences and clinical care, compares quality of care for women and men, and looks at racial and ethnic differences in quality of care among women and men separately for Medicare Advantage plans.[1005]
- The *Rural-Urban Disparities in Health Care in Medicare Report* which details rural-urban differences in health care experiences and clinical care.[1006]
- The *Standardized Patient Assessment Data Elements* for certain post-acute care Quality Reporting Programs, which now includes data reporting for race and ethnicity and preferred language, in addition to screening questions for social needs (84 FR 42536 through 42588).
- *The CMS Innovation Center's Accountable Health Communities Model* which includes standardized collection of health-related social needs data.
- *The Guide to Reducing Disparities* which provides an overview of key issues related to disparities in readmissions and reviews set of activities that can help hospital leaders

[989] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[990] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospital qualityinits/downloads/medicare-hospital-quality-chartbook-2014.pdf.*

[991] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[992] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[993] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[994] Health and Human Services. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[995] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[996] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[997] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[998] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[999] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government.*

[1000] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[1001] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[1002] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[1003] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1004] *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH-Mapping-Medicare-Disparities.*

[1005] *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[1006] Centers for Medicare & Medicaid Services. Rural-Urban Disparities in Health Care in Medicare. 2019. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Urban-Disparities-in-Health-Care-in-Medicare-Report.pdf.*

reduce readmissions in diverse populations.[1007]

- The CMS State Health Official Letter, *Opportunities in Medicaid and CHIP to Address Social Determinants of Health (SDOH) released on January 7, 2021,* which outlines opportunities under Medicaid and the Children's Health Insurance program (CHIP) to better address SDOH and to support states with designing programs, benefits, and services that can more effectively improve population health, reduce disability, and lower overall health care costs in the Medicaid and CHIP programs by addressing SDOH.[1008]
- *The CMS Disparity Methods* which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmissions Reduction Program (see 84 FR 42496 through 42500 for a discussion of using stratified data in additional measures).

These programs are informed by reports by the National Academies of Science, Engineering and Medicine (NASEM) [1009] and the Office of the Assistant Secretary for Planning and Evaluation (ASPE) [1010] which have examined the influence of social risk factors on several of our quality programs. In this RFI, we address only the eighth initiative as previously listed, the CMS Disparity Methods. We discuss the implementation of these methods to date and present considerations for continuing to improve and expand use of these methods to provide providers and ultimately consumers with actionable information on disparities in health care quality to support efforts at closing the equity gap.

2. Current CMS Disparity Methods

We first sought public comment on potential public reporting of hospital quality measure data stratified by social risk factors in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25199). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), we considered potential confidential reporting of the Hospital Inpatient Quality Reporting (IQR) Program Pneumonia Readmission (NQF#0506) and Pneumonia Mortality (NQF#0468) measures stratified by dual-eligibility status. We initially focused on stratification by dual eligibility which is consistent with recommendations from ASPE's First Report to Congress which was required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 (Pub. L. 113–185).[1011] This report found that in the context of value-based purchasing (VBP) programs, dual eligibility, as an indicator of social risk, was among the most powerful predictors of poor health outcomes among those social risk factors that ASPE examined and tested. We also solicited feedback on the two potential methods for illuminating differences in outcomes rates among patient groups within a provider's patient population that would allow for a comparison of those differences, or disparities, across providers. A first method (the Within-Hospital disparity method) promotes quality improvement by calculating differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. This method also allows for a comparison of the magnitude of disparity across hospitals, so hospitals could assess how well they are closing disparity gaps compared to other hospitals. The second methodological approach (the Across-Hospital method) is complementary and assesses hospitals' outcome rates for dual-eligible patients only, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. We also specifically solicited feedback on which social risk factors provide the most valuable information to stakeholders. Overall, comments supported the use of dual eligibility as a proxy for social risk, although commenters also suggested investigation of additional social risk factors, and we continue to consider which risk factors provide the most valuable information to stakeholders.

In the FY 2019 IPPS/LTCH PPS final rule (82 FR 41597 through 41601) we finalized plans to provide confidential hospital-specific reports (HSRs) containing stratified results of the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality (NQF #0468) measures including both the Across-Hospital Disparity Method and the Within-Hospital Disparity Methods (disparity methods) stratified by full-benefit dual eligibility. In the FY 2019 final rule (83 FR 41554 through 41556) we also removed six condition/procedure-specific readmission measures, including the Pneumonia Readmission Measure (NQF #0506) (83 FR 41544 through 41556) and five mortality measures, including the Pneumonia Mortality measures (NQF #0468) (83 FR 41556 through 41558) from the Hospital IQR Program. The Pneumonia Readmission measure (NQF #0506) and the other condition/procedure-specific readmission measures remained in the HRRP. We also noted in the FY 2019 final rule, that for the future, we were considering: (1) Expanding our efforts to provide stratified data in confidential HSRs for other measures; (2) including other social risk factors beyond dual eligible status in confidential HSRs; and (3) eventually, making stratified data publicly available on the *Hospital Compare* (now *Care Compare*) website or successor website (83 FR 41598). In 2019 we provided hospitals with results of the Pneumonia Readmission measure (NQF #0506) stratified using full-benefit dual eligibility. We provided this information in annual confidential HSRs for claims-based measures.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42388 through 42390) we invited public comment on our proposal to apply the disparity methods to additional outcome measures for confidential reporting to the five additional condition/procedure-specific readmission measures: (1) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (AMI Readmission measure); (2) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (CABG Readmission measure); (3) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (COPD Readmission measure); (4) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (HF Readmission measure); and (5) Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee

[1007] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[1008] CMS State Health Official Letter. Opportunities in Medicaid and CHIP to Address Social Determinants of Health. January 7, 2021. Available at *https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf.*

[1009] National Academies of Sciences, Engineering, and Medicine. 2016. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21858.*

[1010] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[1011] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

Arthroplasty (TKA) (NQF #1551) (THA/TKA Readmission measure). Many commenters supported our proposal to continue to provide hospitals with confidential hospital-specific reports on the Pneumonia Readmission measure using the two disparity methods and to expand that effort to include the five additional condition/procedure-specific readmission measures. Commenters expressed concern with stratifying measure data based only on dual eligibility status and recommended that we continue to consider and refine additional social risk factors for stratification in confidential HSRs and specifically consider additional factors that might affect outcomes or result in higher spending, including race, ethnicity, geographic area, sex, disability, education, and access to care. One commenter expressed concern about the reliability of race and ethnicity data if CMS should consider stratifying hospital quality data by such factors and recommended that CMS develop a proposal to improve the collection of race and ethnicity data or to promote public transparency using data that are of mixed quality, before reporting such data publicly. We replied that we focused our initial efforts on providing disparity results based on dual eligible status because of strong evidence demonstrating worse health outcomes among dual eligible Medicare beneficiaries, and because reliable information is readily available in our administrative claims. We also noted that we continue to explore opportunities to account for additional social risk factors in the future, including evaluating new sources of social risk factor data and how to capture such data, engaging with stakeholders, and examining the availability and feasibility of account for social risk factors which might influence quality outcome measures.

ASPE's Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,[1012] required by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, released in March 2020, recommended among other things, that CMS should explore ways to encourage providers to collect social risk information, that quality reporting programs should include health equity measures, and that quality and resource use measures should be reported separately for dually enrolled beneficiaries and other beneficiaries.

In 2020, we provided hospitals with results of each of the six condition/procedure-specific readmission measures, for which reporting requirements were met, stratified using full-benefit dual eligibility. We provided this information in annual confidential HSRs for claims-based measures. Results were made available for hospitals to download through the secure portal within the QualityNet website each spring. Results for the 2020 confidential reporting period for the CMS Disparity Methods showed worse outcomes for dually eligible beneficiaries across the majority of hospitals for all six condition-specific measures.[1013] These results underscore the importance of continuing to make health care equity information more available to providers to promote quality improvement.

For additional information on the two disparity methods, we refer readers to the technical report available on the Quality Net website (*https://qualitynet.cms.gov/inpatient/measures/disparity-methods/resources#tab2*), as well as the FY 2018 IPPS/LTCH PPS final rule (82 FR 38405 through 38407).

3. Potential Expansion of the CMS Disparity Methods

We are committed to advancing health equity by improving data collection to better measure and analyze disparities across programs and policies.[1014] As we described previously, we have been considering, among other things, expanding our efforts to provide stratified data for additional social risk factors and measures, optimizing the ease-of-use of the results, enhancing public transparency of equity results, and building towards provider accountability for health equity. We are seeking public comment on three potential future expansions of the CMS Disparity Methods, including: (1) Future potential stratification of quality measure results by race and ethnicity, (2) improving demographic data collection; and (3) the potential creation of a Hospital Equity Score to synthesize results across multiple social risk factors.

a. Future Potential Stratification of Quality Measure Results by Race and Ethnicity

The Administration's *Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* directs agencies to assess potential barriers that underserved communities and individuals may face to enrollment in and access to benefits and services in Federal Programs. As summarized previously, studies have shown that among Medicare beneficiaries, racial and ethnic minority persons often experience worse health outcomes, including more frequent hospital readmissions and procedural complications. We are considering expanding the disparity methods to include stratification of the condition/procedure-specific readmission measures by race and ethnicity. The 1997 Office of Management and Budget (OMB) Revisions to the Standards for the Collection of Federal Data on Race and Ethnicity, outlines the racial and ethnic categories which may potentially be used for reporting the disparity methods, which we note are intended to be considered as social and cultural, and not biological or genetic.[1015] The 1997 OMB Standard lists five minimum categories of race: (1) American Indian or Alaska Native; (2) Asian; (3) Black or African American; (4) Native Hawaiian or Other Pacific Islander; (5) and White. In the OMB standards, Hispanic or Latino is the only ethnicity category included, and since race and ethnicity are two separate and distinct concepts, persons who report themselves as Hispanic or Latino can be of any race.[1016] Another example, the ''Race & Ethnicity—CDC'' code system in PHIN Vocabulary Access and Distribution System (VADS) [1017] permits a much more granular structured recording of a patient's race and ethnicity with its inclusion of over 900 concepts for race and ethnicity. The recording and exchange of patient race and ethnicity at such a granular level can facilitate the accurate identification and analysis of health disparities based on race and ethnicity. Further, the ''Race & Ethnicity—CDC'' code system has a hierarchy that rolls up to the OMB minimum categories for race and ethnicity and, thus, supports

[1012] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[1013] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

[1014] Centers for Medicare Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[1015] Revisions to the standards for the classification of Federal data on race and ethnicity. 62 FR 58782–58790.

[1016] *https://www.census.gov/topics/population/hispanic-origin/about.html.*

[1017] *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520.*

aggregation and reporting using the OMB standard. ONC includes both the CDC and OMB standards in its criterion for certified health IT products.[1018] For race and ethnicity, a certified health IT product must be able to express both detailed races and ethnicities using *any* of the 900 plus concepts in the ''Race & Ethnicity—CDC'' code system in the Public Health Information Network (PHIN) Vocabulary Access and Distribution Systems (VADS), as well as aggregate each one of a patient's races and ethnicities to the categories in the OMB standard for race and ethnicity. This approach can reduce burden on providers recording demographics using certified products.

Self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. However, CMS currently does not consistently collect self-reported race and ethnicity for the Medicare program, but instead gets the data from the Social Security Administration (SSA) and the data accuracy and comprehensiveness have proven challenging despite capabilities in the marketplace via certified health IT products. Historical inaccuracies in Federal data systems and limited collection classifications have also contributed to the limited quality of race and ethnicity information in our administrative data systems.[1019] In recent decades, to address these data quality issues, we have undertaken numerous initiatives, including updating data taxonomies and conducting direct mailings to some beneficiaries to enable more comprehensive racial and ethnic identification.[1020] [1021] Despite those efforts, studies reveal varying data accuracy in identification of racial and ethnic groups in Medicare administrative data, with higher sensitivity for correctly identifying White and Black individuals, and lower sensitivity for correctly identifying individuals of Hispanic ethnicity or of Asian/Pacific Islander (API) and American Indian/Alaskan Native race.[1022] Incorrectly classified race or ethnicity may result in overestimation or underestimation in the quality of care received by certain groups of beneficiaries.

We continue to work with Federal and private partners to better collect and leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection [1023] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health, and sponsored several initiatives to statistically estimate race and ethnicity information when it is absent.[1024] The Office of the National Coordinator for Health Information Technology (ONC) included social, psychological, and behavioral standards in the 2015 Edition health information technology certification criteria (2015 Edition), providing interoperability standards (LOINC [Logical Observation Identifiers Names and Codes] and SNOMED CT [Systematized Nomenclature of Medicine—Clinical Terms]) for financial strain, education, social connection and isolation, and others. Additional stakeholder efforts underway to expand capabilities to capture additional social determinants of health data elements include the Gravity Project to identify and harmonize social risk factor data for interoperable electronic health information exchange for EHR fields, as well as proposals to expand the ICD–10 (International Classification of Diseases, Tenth Revision) z-codes, the alphanumeric codes used worldwide to represent diagnoses.[1025]

While development of sustainable and consistent programs to collect data on social determinants of health can be considerable undertakings, we recognize that another method to identify better race and ethnicity data is needed in the short term to address the need for reporting on health equity. In working with our contractors, two algorithms have been developed to *indirectly estimate* the race and ethnicity of Medicare beneficiaries (as described further in the next section). We believe that using indirect estimation can help to overcome the current limitations of demographic information and enable timelier reporting of equity results until longer term collaborations to improve demographic data quality across the health care sector materialize. The use of indirect estimated race and ethnicity for conducting stratified reporting does not place any additional collection or reporting burdens on hospitals as these data are derived using existing administrative and census-linked data.

Indirect estimation relies on a statistical imputation method for inferring a missing variable or improving an imperfect administrative variable using a related set of information that is more readily available.[1026] Indirectly estimated data are most commonly used at the population level (such as the hospital or health plan-level) where aggregated results form a more accurate description of the population than existing, imperfect data sets. These methods often estimate race and ethnicity using a combination of other data sources which are predictive of self-identified race and ethnicity, such as language preference, information about race and ethnicity in our administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood. Indirect estimation has been used in other settings to support population-based equity measurement when self-identified data are not available.[1027]

As described earlier, we previously supported the development of two such methods of indirect estimation of race and ethnicity among Medicare

[1018] See *https://www.healthit.gov/isa/representing-patient-race-and-ethnicity*. For more information about the certification criterion for ''Demographics'' in the ONC Health IT Certification program, see *https://www.healthit.gov/test-method/demographics.*

[1019] Zaslavasky AM, Ayanian JZ, Zaborski LB. The validity of racial and ethnic codes in enrollment data for Medicare beneficiaries. Health Services Research, 2012 Jun (47) (3 Pt 2): 1300–21.

[1020] Filice CE, Joynt KE. Examining Race and Ethnicity Information in Medicare Administrative Data. Med Care. 2017; 55(12):e170–e176. doi:10.1097/MLR.0000000000000608.

[1021] Eicheldinger, C., & Bonito, A. (2008). More accurate racial and ethnic codes for Medicare administrative data. Health Care Financing Review, 29(3), 27–42.

[1022] Zaslavsky AM, Ayanian JZ, Zaborski LB. The validity of race and ethnicity in enrollment data for Medicare beneficiaries. Health Serv Res. 2012 Jun;47(3 Pt 2):1300–21.

[1023] Centers for Medicare & Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[1024] *https://pubmed.ncbi.nlm.nih.gov/18567241/, https://pubmed.ncbi.nlm.nih.gov/30506674/,* Eicheldinger C, Bonito A. More accurate racial and ethnic codes for Medicare administrative data. *Health Care Financ Rev.* 2008; 29(3):27–42. Haas A, Elliott MN, Dembosky JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res.* 2019; 54(1):13–23. doi:10.1111/1475–6773.13099.

[1025] *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

[1026] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

[1027] Institute of Medicine. 2009. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: The National Academies Press. Available at: *https://www.ahrq.gov/sites/default/files/publications/files/iomracereport.pdf.*

beneficiaries. One indirect estimation approach developed by our contractor uses Medicare administrative data, first name and surname matching, derived from the U.S. Census and other sources, with beneficiary language preference, State of residence, and the source of the race and ethnicity code in Medicare administrative data to reclassify some beneficiaries as Hispanic or Asian/Pacific Islander (API).[1028] In recent years, we have also worked with another contractor to develop a new approach, the Medicare Bayesian Improved Surname Geocoding (MBISG), which combines Medicare administrative data, first and surname matching, geocoded residential address linked to the 2010 U.S. Census, and uses both Bayesian updating and multinomial logistic regression to estimate the probability of belonging to each of six racial/ethnic groups.[1029]

The MBISG model is currently used to conduct the national, contract-level, stratified reporting of Medicare Part C & D performance data for Medicare Advantage Plans by race and ethnicity.[1030] Validation testing reveals concordance of 0.88–0.95 between indirectly estimated and self-report among individuals who identify as White, Black, Hispanic and API for the MIBSG version 2.0 and concordance with self-reported race and ethnicity of 0.96–0.99 for these same groups for MBISG version 2.1.[1031] [1032] The algorithms under consideration are considerably less accurate for individuals who self-identify as American Indian/Alaskan Native or multiracial.[1033] Indirect estimation can be a statistically reliable approach for calculating population-level equity results for groups of individuals (such as the hospital-level) and is not intended, nor being considered, as an approach for inferring the race and ethnicity of an individual.

However, despite the high degree of statistical accuracy of the indirect estimation algorithms under consideration, there remains the small risk of unintentionally introducing measurement bias. For example, if the indirect estimation is not as accurate in correctly estimating race and ethnicity in certain geographies or populations it could lead to some bias in the method results. Such bias might result in slight overestimation or underestimation of the quality of care received by a given group. We feel this amount of bias is considerably less than would be expected if stratified reporting were conducted using the race and ethnicity currently contained in our administrative data. Indirect estimation of race and ethnicity is envisioned as an intermediate step, filling the pressing need for more accurate demographic information for the purposes of exploring inequities in service delivery, while allowing newer approaches, as described in the next section, for improving demographic data collection to progress. We are interested in learning more about, and soliciting comments about, the potential benefits and challenges associated with measuring hospital equity using an imputation algorithm to enhance existing administrative data quality for race and ethnicity until self-reported information is sufficiently available.

b. Improving Demographic Data Collection

Stratified hospital-level reporting using indirectly estimated race and ethnicity would represent an important advance in our ability to provide accurate equity reports to hospitals. However, self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity. The CMS Quality Strategy outlines our commitment to strengthening infrastructure and data systems by ensuring that standardized demographic information is collected to identify disparities in health care delivery outcomes.[1034] Collection and sharing of a standardized set of social, psychological, and behavioral data by hospitals, including race and ethnicity, using electronic data definitions which permit nationwide, interoperable health information exchange, can significantly enhance the accuracy and robustness of our equity reporting.[1035] This could potentially include expansion of stratified reporting to additional social factors, such as language preference and disability status, where accuracy of administrative data is currently limited. We are mindful that additional resources, including data collection and staff training may be necessary to ensure that conditions are created whereby all patients are comfortable answering all demographic questions, and that individual preferences for non-response are maintained.

We note that eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program must use certified EHR technology (CEHRT) that has been certified to the 2015 Edition of health IT certification criteria. As noted previously, the certification criterion for Demographics under the 2015 Edition (at 45 CFR 170.315(a)(5)) supports collection of data using both the OMB standards for collecting data on race and ethnicity as well as the more granular ''Race & Ethnicity—CDC'' standard. In the 2020 ONC 21st Century Cures Act final rule, ONC also adopted a new framework for the core data set which certified health IT products must exchange, called the United States Core Data for Interoperability (USCDI) (85 FR 25669). The USCDI incorporates the demographic data and associated code sets finalized for the 2015 Edition certification criteria.

As noted previously, ONC also finalized a certification criterion in the 2015 Edition which supports a certified

[1028] Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008. Available at: *https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.233.6403&rep=rep1&type=pdf.*

[1029] Haas, A., Elliott, M. et al (2018). Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Services Research,* 54:13–23 and Bonito AJ, Bann C, Eicheldinger C, Carpenter L. Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries. Final Report, Sub-Task 2. (Prepared by RTI International for the Centers for Medicare and Medicaid Services through an interagency agreement with the Agency for Healthcare Research and Policy, under Contract No. 500–00–0024, Task No. 21) AHRQ Publication No. 08–0029–EF. Rockville, MD, Agency for Healthcare Research and Quality. January 2008. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338295/pdf/HESR-54-13.pdf.*

[1030] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[1031] The Office of Minority Health (2020). Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage, The Centers for Medicare and Medicaid Services, (pg vii). *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[1032] MBISG 2.1 validation results performed under contract #GS–10F–0012Y/HHSM–500–2016–00097G. Pending public release of the 2021 Part C and D Performance Data Stratified by Race, Ethnicity, and Gender Report, available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/research-and-data/statistics-and-data/stratified-reporting.*

[1033] Haas, A, Elliott, MN, Dembosky, JW, et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. Health Serv Res. 2019; 54: 13–23. *https://doi.org/10.1111/1475-6773.13099.*

[1034] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[1035] The Office of the National Coordinator for Health Information Technology. United State Core Data for Interoperability Draft Version 2. 2021. Available at: *https://www.healthit.gov/isa/sites/isa/files/2021-01/Draft-USCDI-Version-2-January-2021-Final.pdf.*

health IT product's ability to collect social, psychological, and behavioral data (at 45 CFR 170.315(a)(15)). However, this functionality is not included as part of the certified EHR technology required by the Promoting Interoperability program. While the technical functionality exists to achieve the gold standard of data collection, we understand challenges and barriers exist in using the technologies with these capabilities.

We are interested in learning about, and are soliciting comments on, current data collection practices by hospitals to capture demographic data elements (such as race, ethnicity, sex, sexual orientation, and gender identity (SOGI), language preference, tribal membership, and disability status). Further, we are interested in potential challenges facing hospital collection, at the time of admission, of a minimum set of demographic data elements in alignment with national data collection standards (such as the standards finalized by the Affordable Care Act [1036]) and standards for interoperable exchange (such as the United States Core Data for Interoperability incorporated into certified health IT products as part of the 2015 Edition of health IT certification criteria [1037]). Advancing data interoperability through collection of a minimum set of demographic data collection, and incorporation of this demographic information into quality measure specifications, has the potential for improving the robustness of the disparity method results, potentially permitting reporting using more accurate, self-reported, information, such as race and ethnicity, and expanding reporting to additional dimensions of equity, including stratified reporting by disability status.

c. Potential Creation of a Hospital Equity Score To Synthesize Results Across Multiple Social Risk Factors

As we previously described, we are considering expanding the disparity methods to include two social risk factors (dual eligibility which is currently reported and race/ethnicity, which is considered here in this RFI). This approach would improve the comprehensiveness of health equity information provided to hospitals. Aggregated results from multiple measures and multiple social factors, using output from the disparity methods, in the format of a summary score, can improve the usefulness of the equity results. In working with our contractors, we recently developed an equity summary score for Medicare Advantage contracts/plans, the Health Equity Summary Score (HESS), with application to stratified reporting using two social risk factors: Dual eligibility and race and ethnicity, as described in *Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score.*[1038]

The HESS calculates standardized and combined performance scores synthesized across the two social risk factors. The HESS also combines results of the within-plan method (similar to the Within-Hospital method) and across-plan method (similar to the Across-Hospital method) across multiple performance measures.[1039]

We are considering creating a *Hospital Equity Score,* not yet developed, which would be modeled off the HESS, but adapted to the context of risk-adjusted hospital outcome measures and potentially other hospital quality measures used in CMS programs. We envision that the *Hospital Equity Score* would synthesize results for a range of measures and use multiple social risk factors which have been reported to hospitals as part of the CMS Disparity Methods. We believe that creation of the *Hospital Equity Score* has the potential to supplement the overall measure data already reporting on the *Care Compare* or successor website, by providing easy to interpret information regarding disparities measured within individual hospitals and across hospitals nationally. A summary score would be useful to decrease burden by minimizing the number of measure results provided and providing an overall indicator of equity.

The *Hospital Equity Score* under consideration would potentially—

- Summarize hospital performance across multiple social risk factors (initially dual eligibility and race and ethnicity, as described previously); and
- Summarize hospital performance across the two disparity methods (that is, the Within-Hospital Disparity Method and the Across-Hospital Disparity Method) and potentially multiple measures.

Prior to any potential future public reporting, if we determine that a *Hospital Equity Score* can be feasibly and accurately calculated, we intend to initially provide results of the *Hospital Equity Score* in confidential HSRs which hospitals will be able download. Any potential future proposal to display the *Hospital Equity Score* on the *Care Compare* or successor website would be made through future rulemaking.

4. Solicitation of Public Comment

We are currently seeking comment on the possibility of expanding our current disparities methods to include reporting by race and ethnicity using indirect estimation. We are also seeking comment on the possibility of hospital collection of standardized demographic information for the purposes of potentially incorporating into measure specifications to permit more robust equity measurement. Additionally, we are seeking comment on the design of a Hospital Equity Score for calculating results across multiple social risk factors and measures, including race/ethnicity and dual eligibility. Any data pertaining to these areas that are recommended for collection for measure reporting for a CMS program and any potential public disclosure on *Care Compare* or successor website would be addressed through separate and future notice- and-comment rulemaking. We plan to continue working with ASPE, hospitals, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all patients and minimizing unintended consequences. We look forward to receiving feedback on these topics and note for readers that responses to the RFI will not directly impact payment decisions. We also note our intention for additional RFI or rulemaking on this topic in the future.

Specifically, we are inviting public comment on the following:

- Future Potential Stratification of Quality Measure Results by Race and Ethnicity

++ The potential future application of an algorithm to indirectly estimate race and ethnicity to permit stratification of measures (in addition to dual-eligibility) for hospital—level disparity reporting, until more accurate forms of self-identified demographic information are available.

++ Appropriate privacy safeguards with respect to data produced from the indirect estimation of race and ethnicity to ensure that such data is properly identified if/when it is shared with providers.

++ Ways to address the challenges of defining and collecting, accurate and

[1036] *https://minorityhealth.hhs.gov/assets/pdf/checked/1/Fact_Sheet_Section_4302.pdf.*

[1037] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[1038] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019. doi:10.1007/s11606–019–05473–x.

[1039] Agniel D, Martino SC, Burkhart Q, et al. Incentivizing Excellent Care to At-Risk Groups with a Health Equity Summary Score. J Gen Intern Med. Published online November 11, 2019. doi:10.1007/s11606–019–05473–x.

standardized, self-identified demographic information, including information on race and ethnicity, disability, and language preference for the purposes of reporting, measure stratification, and other data collection efforts relating to quality.

++ Recommendations for other types of feasibly collected data elements for measuring disadvantage and discrimination, for the purposes of quality reporting and measure stratification, in addition to, or in combination with, race and ethnicity.

++ Recommendations for other types of quality measures or measurement domains, in addition to readmission measures, to prioritize for stratified reporting by dual eligibility, race and ethnicity, and disability.

++ Examples of approaches, methods, research, and/or considerations for use of data-driven technologies that do not facilitate exacerbation of health inequities, recognizing that biases may occur in algorithms or be encoded in datasets.

• Improving Demographic Data Collection

++ Experiences of users of certified health IT regarding local adoption of practices for collection of demographic elements, the perceived value of using these data for improving decision-making and care delivery, and the potential challenges and benefits of collecting and using more granular, structured demographic information, such as the ''Race & Ethnicity—CDC'' code system.

++ The possible collection of a minimum set of demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, tribal membership, and disability status), by hospitals at the time of admission, using electronic data definitions which permit nationwide, interoperable health information exchange, for the purposes of incorporating into measure specifications and other data collection efforts relating to quality.

• Potential Creation of a Hospital Equity Score To Synthesize Results Across Multiple Social Risk Factors

++ The possible creation and confidential reporting of a *Hospital Equity Score* to synthesize results across multiple social risk factors and disparity measures.

++ Interventions hospitals could institute to improve a low hospital equity score and how improved demographic data could assist with these efforts.

C. Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

The Hospital IQR Program strives to put patients first by ensuring they are empowered to make decisions about their own healthcare along with their clinicians by using information from data-driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across the U.S. Department of Health and Human Services (HHS), we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. The adoption of widely agreed upon quality and cost measures supports this effort. We work with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless a different or more limited time period is finalized in the measure proposals. Measures are retained unless we propose to remove, suspend, or replace the measures. We are not proposing any changes to these policies in this proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors. We are not proposing any changes to our policies regarding measure removal in this proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework, our objectives under this Framework for quality measurement, and the quality topics that we have identified as high-impact measurement areas that are relevant and meaningful to both patients

and providers. We are not proposing any changes to these policies in this proposed rule. We also note that the Hospital IQR Program must first adopt measures and publicly report them on the *Care Compare* and/or its successor website for at least one year before the Hospital VBP Program is able to adopt them. We view the value-based purchasing programs, including the Hospital VBP Program, as the next step in promoting higher quality care for Medicare beneficiaries by transforming Medicare from a passive payer of claims into an active purchaser of quality healthcare for its beneficiaries.

5. Proposals To Adopt New Measures for the Hospital IQR Program Measure Set

In this proposed rule, we are proposing to adopt five new measures: (1) Maternal Morbidity Structural Measure, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination; (2) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM) measure beginning with a voluntary submission period which would run from July 1, 2022 through June 30, 2023, and followed by mandatory reporting beginning with the reporting period which runs July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination; (3) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination; (4) Hospital Harm-Severe Hypoglycemia eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination; and (5) Hospital Harm-Severe Hyperglycemia eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination. The following sections discuss these proposals in more detail.

a. Proposed Maternal Morbidity Structural Measure Beginning With a Shortened Reporting Period From October 1, 2021 Through December 31, 2021, Affecting the FY 2023 Payment Determination Followed By Annual Reporting Periods for Subsequent Years

(1) Background

Despite the highest rate of spending on maternity care, the U.S. ranks worse than most other developed nations in preventing pregnancy-related deaths.[1040] The Maternal Mortality Rate in the U.S. increased from 17 deaths per 100,000 live births in 1990 to 26 deaths per 100,000 live births in 2015.[1041] Similar to maternal mortality, maternal morbidity is highly preventable.[1042] Without proper treatment, maternal morbidities can lead to mortality.[1043] Researchers have found that the presence of select maternal morbidities such as chronic hypertension and preeclampsia were strongly associated with increased odds of mortality at the time of delivery.[1044] Timely and appropriate treatment of maternal morbidities is imperative to prevent complications that can lead to maternal mortality.[1045]

One of the main factors contributing to the increase in maternal morbidity and mortality is inconsistent obstetric practice.[1046] Hospitals in the U.S. lack standardized protocols to address obstetric emergencies and complications that arise during pregnancy and childbirth.[1047] A standardized approach to address these concerns is necessary to effectively manage obstetric emergencies and complications.[1048] Thus, assessing hospital engagement in implementing standardized protocols is essential to efficiently manage maternal morbidity nationally. Addressing this maternal health crisis and improving maternal health is a priority and a quality improvement goal for CMS.

Therefore, in this proposed rule, we are proposing to adopt the Maternal Morbidity Structural Measure (Maternal Morbidity measure), beginning with a shortened reporting period running from October 1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, to help address this maternal health crisis. After which, the reporting period would be 12 months beginning with the FY 2024 payment determination (reporting period January 1, 2022 through December 31, 2022) and for subsequent years. We developed this structural measure to determine hospital participation in a State or national Perinatal Quality Improvement (QI) Collaborative initiative and implementation of patient safety practices or bundles within that QI initiative. We define a state or national Perinatal Quality Improvement Collaborative as a statewide or a multi-State network working to improve women's health and maternal health outcomes by addressing the quality and safety of maternity care. These collaboratives employ clinical practices and processes to address gaps in care, as well as collect and review performance data. These collaboratives also include implementation of evidence-based maternity safety bundles and/or patient safety practices to improve patient outcomes and reduce maternal mortality and severe maternal morbidity. Hospital participation in quality improvement collaboratives has been shown to be effective in appropriately managing maternal morbidity conditions that may lead to mortality or other adverse consequences.[1049] This measure would: (1) Determine the number of hospitals currently participating in a structured State or national Perinatal QI Collaborative; and (2) determine whether hospitals are implementing the safety practices or bundles included as part of these QI initiatives.

State level QI programs have been shown to be effective in decreasing maternal morbidity.[1050] One controlled trial conducted at 147 California hospitals utilizing a QI toolkit, which

[1040] Maternal Health in the United States. Maternal Health Task Force at the Harvard Chan School. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/.*

[1041] Maternal Health in the United States. Maternal Health Task Force at the Harvard Chan School. Available at: *https://www.mhtf.org/topics/maternal-health-in-the-united-states/.*

[1042] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. *American Journal of Obstetrics and Gynecology,* 215(3):B17.

[1043] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. *American Journal of Obstetrics and Gynecology,* 215(3):B17–B22.

[1044] Campbell, K.H., Savitz, D., Werner, E.F., Pettker, C.M., Goffman, D., Chazotte, C., Lipkind, H.S. (2013). Maternal Morbidity and Risk of Death at Delivery Hospitalization. *Obstetrics and Gynecology,* 122(3): 627–633. *https://journals.lww.com/greenjournal/fulltext/2013/09000/Maternal_Morbidity_and_Risk_of_Death_at_Delivery.20.aspx.*

[1045] Kilpatrick, S.K., Ecker, J.L. (2016). Severe Maternal Morbidity: Screening and Review. *American Journal of Obstetrics and Gynecology,* 215(3): B17.

[1046] World Health Organization (WHO), Bulletin of the WHO. Maternal Mortality and Morbidity in the United States. Available at: *https://www.who.int/bulletin/volumes/93/3/14-148627/en/.*

[1047] World Health Organization (WHO), Bulletin of the WHO. Maternal Mortality and Morbidity in the United States. Available at: *https://www.who.int/bulletin/volumes/93/3/14-148627/en/.*

[1048] World Health Organization (WHO), Bulletin of the WHO. Maternal Mortality and Morbidity in the United States. Available at: *https://www.who.int/bulletin/volumes/93/3/14-148627/en/.*

[1049] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. *American Journal of Obstetrics and Gynecology,* 216(3): 298.e1. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

[1050] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. *American Journal of Obstetrics and Gynecology,* 216(3): 298.e4. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

was a patient safety bundle for obstetrical hemorrhage, found that hospitals that had implemented the QI toolkit showed a 20.8 percent decrease in obstetrical hemorrhage versus a 1.2 percent reduction at non-participating hospitals.[1051] We believe the Maternal Morbidity measure will help us better understand the current efforts of hospitals to improve nationwide inpatient maternal morbidity.

The existing literature on maternal morbidity also documents how patient safety practices and bundles utilized in statewide and national Perinatal Quality Collaborative programs can improve maternal outcomes.[1052] The implementation of triggers, bundles, protocols, and checklists have been shown to improve the quality and safety of obstetric care delivery.[1053] Triggers are used to identify an event that mandates further action by a healthcare professional, which then facilitates timely intervention and patient safety.[1054] Examples of triggers include hypertension greater than 180/110 and fever (temperature over 38.5°C).[1055] Bundles are a collection of interventions such as checklists, protocols, and educational materials that target a specific morbidity such as hypertension or hemorrhage.[1056] Protocols are precise plans of action for specific clinical scenarios and serve to augment memory and limit human error in demanding environments such as labor and delivery units.[1057] These evidence-based tools also facilitate improvements in timely diagnosis and treatment that serve to prevent morbidity.[1058] This measure would allow us to assess hospital participation in QI collaborative programs in the inpatient setting and the implementation of safety practices or bundles.

At this time, CMS quality reporting programs do not include quality measures that specifically address maternal morbidity. The current Hospital IQR Program measure set includes the PC–01 measure for Elective Deliveries (77 FR 53530), and the Merit-Based Incentive Payment System (MIPS) in the Quality Payment Program includes measures for Elective Delivery or Early Induction and Post-Partum Follow-up and Care Coordination (81 FR 77625). While these measures contribute to improving maternal health, they do not specifically address maternal morbidity. Therefore, we believe it is important to adopt this measure into the Hospital IQR Program.

Under CMS' Meaningful Measures Framework, the Maternal Morbidity measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' [1059] Because many of the factors contributing to maternal morbidity are preventable, this measure would be the first step toward assessing the current landscape of QI participation and implementation of patient safety practices or bundles with the objective of reducing maternal morbidity, and in turn, maternal mortality.

(2) Overview of Measure

To report on this measure, hospitals would respond to a two-part question: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?'' Hospitals would then choose from the following response options: (A) ''Yes''; (B) ''No''; or (C) ''N/A (our hospital does not provide inpatient labor/delivery care)'' and would submit responses once a year via a CMS-approved web-based tool on the QualityNet website.

The Maternal Morbidity measure was included on the publicly available ''2019 Measures under Consideration Spreadsheet'' [1060] (MUC List), a list of measures under consideration for use in various Medicare programs. The Measure Applications Partnership (MAP) Hospital Workgroup, which the MAP Coordinating Committee oversees, reviewed the MUC List and the Maternal Morbidity measure (MUC2019–114) in detail on December 4, 2019.[1061] The MAP Hospital Workgroup reviewed the measure as: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, which includes implementation of patient safety practices or bundles to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?'' [1062] The MAP Hospital Workgroup's preliminary recommendation was to not support MUC2019–114 Maternal Morbidity for rulemaking, with potential for mitigation.[1063]

The potential mitigating factors identified by the MAP Hospital Workgroup were to adjust the language of the question to clarify that the hospital is expected both to attest to participation in a quality improvement initiative as well as to implement patient safety practices or bundles to

[1051] Main, E.K., Cape, V., Abreo, A., Vasher, J., Woods, A., Carpenter, A., Gould, J.B. (2017). Reduction of Severe Maternal Morbidity from Hemorrhage Using a State Perinatal Quality Collaborative. *American Journal of Obstetrics and Gynecology,* 216(3): 298.e4. Available at: *https://www.ncbi.nlm.nih.gov/pubmed/28153661.*

[1052] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists-What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[1053] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists-What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 449–450.

[1054] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists-What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[1055] Forster, Alan J. MD, FRCPC; Fung, Irene; Caughey, Sharon MD, FRCPC; Oppenheimer, Lawrence MD, FRCPC; Beach, Cathy; Shojania, Kaveh G. MD; van Walraven, Carl MD, FRCPC, MSc. 2006. Adverse Events Detected by Clinical Surveillance on an Obstetric Service. Obstetrics and Gynecology, 108(5): 1073–1083.

[1056] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists-What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[1057] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists-What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[1058] Arora, K.S., Shields, L.E., Grobman, W.A., D'Alto, M.E. (2016). Triggers, Bundles, Protocols, and Checklists-What Every Maternal Care Provider Needs to Know. American Journal of Obstetrics and Gynecology, 214(4): 444–451.

[1059] The Maternal Morbidity Measure addresses the quality priority of ''Make Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measures Area of ''Preventable Healthcare Harm.'' More information on CMS' Meaningful Measures Framework is available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1060] 2019 Measures Under Consideration. Information available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91406.*

[1061] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[1062] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[1063] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

address complications and that the Maternal Morbidity measure go through the NQF endorsement process. The MAP Hospital Workgroup members suggested replacing ''which includes implementation of patient safety practices or bundles'' with ''and has implemented patient safety practices or bundles'' to clarify that the intent of the measure is both to identify hospitals that participate in a QI program *and* implement specific bundles known to improve outcomes.[1064] To address the MAP's feedback regarding the measure's usability, we made the aforementioned change to the measure, thereby clarifying that the measure would assess participation in QI initiatives *and* the implementation of patient safety practices or bundles to address complications (rather than assessing participation in a QI initiative alone).

The MAP Coordinating Committee, which provides direction to the MAP workgroups, reconvened on January 15, 2020 and reviewed MUC2019–114 Maternal Morbidity measure for rulemaking in detail.[1065] The MAP Coordinating Committee reviewed the measure as: ''Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care, and has implemented patient safety practices or bundles to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?'' [1066] Upon the review of the measure, the MAP Coordinating Committee conditionally supported MUC2019–114 Maternal Morbidity for rulemaking.[1067]

The conditions identified by the MAP Coordinating Committee included adjusting the language of the attestation question to clarify that the hospital is expected both to attest to participation in a quality improvement initiative as well as actually implement patient safety practices or bundles to address complications.[1068] In response to this recommendation, we adjusted the language of the attestation to clarify that answering ''Yes'' to the attestation reflects a yes response to both components of the question.

The MAP Coordinating Committee included an additional condition that we allow multi-hospital quality improvement collaborative participation, in addition to statewide or national collaboratives, to account for programs sponsored by large health systems.[1069] We considered this, but ultimately concluded that those programs should not be included because they are not as well defined as State and national collaboratives.

The MAP Coordinating Committee also recommended adding information to the response options to clarify what constitutes a ''yes, no, or n/a'' response.[1070] In response to this recommendation, we plan to include additional educational and clarifying detail on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Such additional educational and clarifying detail would explain that a hospital participating in a statewide or national Perinatal QI Collaborative, such as the California Maternal Quality Care Collaborative or the Alliance for Innovation on Maternal Health (AIM) program, that has actively implemented patient care safety practices and/or bundles would select ''yes.'' A hospital that neither participates in a statewide or national Perinatal QI Collaborative, such as those previously noted, nor has actively implemented patient safety care practices and/or bundles, would select ''no.'' A hospital that participates in a statewide or national Perinatal QI Collaborative, but has not actively implemented patient care safety practices and/or bundles would select ''no.'' Hospitals that do not provide inpatient labor and delivery care services would select ''n/a.''

Lastly, the MAP Coordinating Committee added a condition that the Maternal Morbidity measure should go through the NQF endorsement process and receive endorsement.[1071] The MAP Coordinating Committee underscored that maternal morbidity is increasing at an alarming rate in the U.S., nearly doubling in the last decade.[1072] With no quality measures that address maternal morbidity, the MAP Coordinating Committee strongly supported our attempts to address this healthcare crisis through measurement.[1073]

Section 1886(b)(3)(B)(IX)(bb) of the Act provides an exception that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed NQF-endorsed measures and were unable to identify any other NQF-endorsed measures that addressed maternal morbidity through hospital participation in State or national perinatal quality collaboratives and the implementation of associated bundles or practices. We found no other feasible and practical measures on the topic of maternal health, therefore we believe the exception in Section 1886(b)(3)(B)(IX)(bb) of the Act applies.

(3) Data Submission and Reporting

We are proposing to begin with a shortened reporting period before transitioning to full year reporting periods to get a preliminary gauge of hospital participation in QI initiatives in a timely manner. Specifically, for the CY 2021 reporting period/FY 2023 payment determination, we are proposing a shortened reporting period: October 1, 2021 through December 31, 2021. Beginning with the CY 2022 reporting period/FY 2024 payment determination and for subsequent years, we are proposing that the reporting period would be: January 1 through December 31.

[1064] National Quality Forum. Measure Applications Partnership (MAP) 2020 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *qualityforum.org/map/.*

[1065] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1066] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1067] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1068] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1069] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1070] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1071] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1072] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1073] National Quality Forum. Measure Applications Partnership (MAP) 2019–2020 Final Recommendations. Available at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

We propose to collect this data once a year via a CMS-approved web-based data collection tool available on the QualityNet website, similar to previous methods of reporting on structural measures. Specifications for the measure will also be posted on the CMS Measure Methodology page with the file name 'Maternal Morbidity Structural Measure Specifications' at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology* . We refer readers to section IX.C.8.i. of the preamble of this proposed rule for more details on our data submission and deadline requirements for structural measures.

We invite public comment on our proposal to adopt the Maternal Morbidity measure beginning with a shortened reporting period running from October 1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, followed by the annual reporting period of January 1 through December 31 for the FY 2024 payment determination and subsequent years.

b. Proposed Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) Voluntary From July 1, 2022 Through June 30, 2023, and Mandatory Beginning July 1, 2023 Through June 30, 2024, Affecting the FY 2026 Payment Determination and Subsequent Years

(1) Background

Estimates using data from 2008 to 2011 suggest that more than 210,000 patients die each year from preventable harm in hospitals.[1074] While we do not expect overall hospital mortality rates to be zero, studies have shown that quality of care relates to mortality within 30 days of hospital admission and that high and variable mortality rates across hospitals indicate opportunities for improvement.[1075] [1076] In addition to the harm to individuals, their families, and caregivers resulting from preventable death, there are also significant financial costs to the healthcare system associated with high and variable mortality rates.[1077] [1078] [1079] While capturing monetary savings for preventable mortality events is challenging, using two recent estimates of the number of deaths due to preventable medical errors, and assuming an average of 10 lost years of life per death (valued at $75,000 per year in lost quality adjusted life years), the annual direct and indirect cost of potentially preventable deaths could be as much as $73.5 to $735 billion.[1080] [1081] [1082]

Condition-specific mortality measures previously adopted into the Hospital IQR and Hospital VBP Programs support quality improvement work targeted toward patients with a set of common medical conditions, such as stroke, heart failure, acute myocardial infarction, or pneumonia. Following the implementation of condition-specific measures, national hospital mortality rates for the measured conditions and/or procedures have declined.[1083] Now, we are interested in also measuring hospital performance across a broader set of patients and across more areas of the hospital.

We developed a hybrid hospital-wide, all-cause, risk-standardized mortality measure that uses claims data to define the measure cohort and a combination of data from electronic health records (EHRs) and claims for risk adjustment (Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (hereinafter referred to as the ''Hybrid HWM measure'')). As more patients are included, a hospital-wide mortality measure also captures the performance for smaller volume hospitals that would otherwise not have sufficient cases to receive measure score or performance information for condition- or procedure-specific mortality measures. As developed, the Hybrid HWM measure addresses the Meaningful Measures Framework quality priority of ''Promoting Effective Treatment to Reduce Risk-Adjusted Mortality.''

The measure developer under contract with us engaged several stakeholder groups, including a Technical Work Group and a Patient and Family Work Group, as well as a national, multi-stakeholder Technical Expert Panel (TEP) consisting of providers, patients, and other stakeholders. These groups provided feedback on the measure concept, outcome, cohort, risk model variables, and the reporting of measure results. The measure developer also solicited stakeholder feedback during measure development as required in the Measures Management System (MMS) Blueprint, including two public comment periods.[1084]

The Hybrid HWM measure uses claims and EHR data to move toward greater use of EHR data for quality measurement. This approach aligns with stakeholder feedback on the importance of including clinical data that is available to the clinical care team at the time treatment is rendered to account for patients' severity of illness, rather than relying solely on data from claims in outcome measures (80 FR 49702 through 49703). This approach also aligns with our goal to move towards digital quality measures (dQMs) to reduce provider data collection burden and to provide more rapid performance feedback on quality measures, as discussed further in section IX.A. of the preamble of this proposed rule.

The Hybrid HWM measure uses a set of core clinical data elements from hospitals' EHRs, similar to those used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879), which was adopted in the Hospital IQR Program in the FY2020 IPPS/LTCH PPS final rule (84 FR 42467). These core clinical data elements are data that hospitals routinely collect, that can be feasibly extracted from hospital EHRs, and that can be utilized as part of specific quality outcome measures.[1085]

[1074] James JT. A new, evidence-based estimate of patient harms associated with hospital care. *Journal of patient safety.* 2013; 9(3):122–128.

[1075] Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. *JAMA.* 2006; 295(16):1912–1920.

[1076] Writing Group for the Checklist—I.C.U. Investigators, Brazilian Research in Intensive Care Network. Effect of a quality improvement intervention with daily round checklists, goal setting, and clinician prompting on mortality of critically ill patients: A randomized clinical trial. *JAMA.* 2016; 315(14):1480–1490.

[1077] Institute of Medicine 2000. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press. Available at: *https://www.nap.edu/resource/9728/To-Err-is-Human-1999--report-brief.pdf.*

[1078] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs. 2011; 30(4):581–589.

[1079] Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. *Journal of health care finance.* 2012; 39(1):39–50.

[1080] Institute of Medicine 2000. To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press. *https://www.nap.edu/resource/9728/To-Err-is-Human-1999--report-brief.pdf.*

[1081] Classen DC, Resar R, Griffin F, et al. 'Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured. Health Affairs. 2011; 30(4):581–589.

[1082] Andel C, Davidow SL, Hollander M, Moreno DA. The economics of health care quality and medical errors. *Journal of health care finance.* 2012; 39(1):39–50.

[1083] Suter LG, Li SX, Grady JN, et al. National patterns of risk-standardized mortality and readmission after hospitalization for acute myocardial infarction, heart failure, and pneumonia: update on publicly reported outcomes measures based on the 2013 release. *Journal of general internal medicine.* 2014; 29(10):1333–1340.

[1084] CMS Measures Management System Blueprint (Blueprint v 16.0). CMS. 2020. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[1085] 2013 Core Clinical Data Elements Technical Report (Version 1.1). 2015. Available at: *https://*

Continued

The data elements are the values for a set of vital signs and common laboratory tests collected at the time the patient initially presents to the hospital. They are used, in addition to claims data, for risk adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are aged between 65 and 94 years). We refer readers to section IX.C.5.b. of the preamble of this proposed rule for more detail on the core clinical data elements used in this measure.

The Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (MUC17–196) was included in a publicly available document entitled ''2017 Measures Under Consideration List'' (available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86527*). The NQF MAP Hospital Workgroup reviewed the measure and noted that it is an important measure for patient safety and that the measure could help reduce deaths due to medical errors.[1086] The MAP expressed concern regarding the potential unintended consequences of unnecessary interventions for patients at the end of life.[1087] The measure developer addressed this issue based upon TEP and patient work group input to remove patients from the cohort who are at the end of life and for whom survival is unlikely to be the goal of care. Specifically, the measure does not include patients enrolled in hospice in the 12 months prior to admission, on admission, or within 2 days of admission. The measure also does not include patients admitted primarily for cancer that are enrolled in hospice at any time during the admission, those admitted primarily for metastatic cancer, and those admitted for specific diagnoses with limited survival.

The MAP additionally requested that the NQF assess whether the measure has appropriate clinical and social risk factors in its risk adjustment model and addresses necessary exclusions. The MAP noted that appropriate risk adjustment and exclusions are necessary to ensure the measure does not disproportionately penalize facilities who may see more complex patients (for example, academic medical centers or safety net providers) or who may have smaller volumes of patients (for example, rural providers). We subsequently submitted the measure for initial endorsement by the NQF and presented analyses to NQF on the impact of social risk factors. Specifically, we assessed the relationship between two social risk factor variables (Medicare-Medicaid dual-eligibility status and the AHRQ-validated socioeconomic status (SES) index score) and the outcome (mortality). We also examined the effect of adding either of these variables into the risk adjustment model on model performance and hospital results. We concluded that correlations between measure scores for models with and without social risk variables were near 1.0, model performance metrics were unchanged, and in most divisions the social risk variables did not have statistically significant association with the risk of mortality in a multivariable model. For the division in which AHRQ SES was associated with mortality, further analyses indicated that adjusting for AHRQ SES would remove hospital-level effects that may reflect lower-quality care provided to patients with low SES status. Based on these results, the measure as endorsed by NQF does not adjust for these social risk factors. The measure is risk-adjusted to account for case mix and service mix differences to prevent disproportionately penalizing facilities.[1088] NQF fully reviewed the measure, including risk adjustment, and endorsed the measure with the risk adjustment, as specified. As presented to NQF, we also noted that all exclusions were determined by careful clinical review and have been made based on clinically relevant decisions and to ensure accurate calculation of the measure. The NQF assessed the exclusions and supported the measure for endorsement.[1089]

The MAP noted this measure used EHR data to support additional factors in the risk adjustment model. Given the variability in EHR systems, the MAP recommended that the NQF standing committee reviewing the measure pay special attention to the ability to consistently obtain EHR data across hospitals. We approached risk variable selection from the perspective of ensuring a parsimonious list of clinical EHR variables that would minimize hospital burden to report the data and provide face validity from a clinical perspective. As candidate risk variables, the core clinical data elements (CCDE) are consistently captured, captured with a standard definition, and entered into the electronic health record in a structured field and can be feasibly extracted, as shown during development and testing, and subsequently presented to NQF.[1090]

The MAP further suggested that condition-specific mortality measures may be more actionable for providers and informative for consumers.[1091] We note that by proposing to adopt the Hybrid HWM measure, we intend to offer additional benefits when reported with condition- or procedure-specific measures, such as: (1) Providing scores and performance information for smaller hospitals; (2) providing an overall hospital-level signal for consumers; and (3) providing yearly updates using a 1-year measurement period, unlike condition- or procedure-specific measures that use 3 years of claims data. Upon review, the MAP expressed their conditional support for rulemaking pending endorsement from the NQF.[1092] Thereafter, the NQF endorsed the Hybrid HWM measure on October 23, 2019.[1093] The MAP also recommended the Hybrid HWM measure have a voluntary reporting period before mandatory implementation.[1094] Our proposal to adopt the Hybrid HWM measure includes beginning with a 1-year voluntary reporting period, as further detailed later in section IX.C.5.b.9.(a). of this proposed rule.

In the FY 2019 IPPS/LTCH PPS final rule, we described the potential future inclusion of the Hybrid HWM measure in the Hospital IQR Program and

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology. Accessed January 2021.

[1086] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[1087] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[1088] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[1089] National Quality Forum. Available at: *https://www.qualityforum.org/QPS/3502*.

[1090] 2013 Core Clinical Data Elements Technical Report (Version 1.1). 2015; *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*. Accessed January 2021.

[1091] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[1092] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

[1093] National Quality Forum. Available at: *https://www.qualityforum.org/QPS/3502*.

[1094] Measure Applications Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals. Washington, DC: NQF; 2018. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87083*.

requested public feedback on the measure. Many stakeholders expressed support for the measure, with many commenters commending the use of EHR data. CMS also responded to stakeholder feedback on the measure methodology, validity, and concept (83 FR 41581 through 41588).

(2) Overview of Measure

The Hybrid HWM measure is an outcome measure that captures hospital-level, risk-standardized mortality within 30 days of hospital admission for most conditions or procedures. It does not have a traditional numerator and denominator like a core process measure (for example, percentage of adult patients with diabetes aged 18 to 75 years receiving one or more hemoglobin A1c tests per year). The measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions (categories of admissions grouped based on similar discharge diagnoses or procedures), with a separate risk model for each of the 15 service-line divisions. The 15 service-line divisions include: Nine non-surgical divisions and six surgical divisions. The non-surgical divisions are: Cancer; cardiac; gastrointestinal; infectious disease; neurology; orthopedics; pulmonary; renal; and other. The surgical divisions are: Cancer; cardiothoracic; general; neurosurgery; orthopedics; and other. Hospitalizations are eligible for inclusion in the measure if the patient was hospitalized at a non-Federal, short-term acute care hospital; results would be publicly reported as part of the Hospital IQR Program.

To compare mortality performance across hospitals, the measure accounts for differences in patient characteristics (patient case mix) as well as differences in the medical services provided and procedures performed by hospitals (hospital service mix). In addition, the Hybrid HWM measure employs a combination of administrative claims data and clinical EHR data to enhance clinical case mix adjustment with additional clinical data. As described previously, the measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions. The overall risk-standardized mortality rate (measure score) will not always reflect a result from each of the 15 divisions for hospitals that do not have a sufficient number of admissions for each service-line division. As a result, some hospitals' overall scores would be based on fewer than 15 divisions because of differences in their case mix.

Our goal is to more comprehensively measure the mortality rates of hospitals, including to improve the ability to measure mortality rates in smaller volume hospitals. The cohort definition attempts to capture as many admissions as possible for which survival would be a reasonable indicator of quality and for which adequate risk adjustment is possible. We assume survival would be a reasonable indicator of quality for admissions fulfilling two criteria: (1) Survival is presumably the primary goal of the patient when they enter the hospital; and (2) the hospital can reasonably influence the patient's chance of survival through quality of care. The Hybrid HWM measure would provide information to hospitals that can facilitate quality improvement efforts and would expand upon condition- and procedure-specific measures by including more settings, types of care, and types of patients. In addition, the Hybrid HWM measure would provide transparency about the quality of care in clinical areas not captured in the current condition- and procedure-specific measures.

Additional information on the specifications of the Hybrid HWM measure can be found in the Core Clinical Data Elements and Hybrid Measure folder on the CMS website at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* and on the eCQI resource center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(3) Data Sources

The Hybrid HWM measure uses three main sources of data for the calculation of the measure: (1) Medicare Part A claims data; (2) a set of core clinical data elements from a hospital's EHR; and (3) mortality status obtained from the Medicare Enrollment Database. The measure uses claims and enrollment data to identify index admissions included in the Hybrid HWM measure cohort, in the risk-adjustment model, and to assess the 30-day mortality outcome. The measure uses one year of Part A Medicare administrative claims data from Medicare FFS beneficiaries aged between 65 and 94 years for the performance period. The measure uses Part A data from the 12 months prior to the index admission for risk adjustment, as well as core clinical data elements from each hospital's EHR for eligible patient admissions. The core clinical data elements are the values for a set of vital signs and common laboratory tests collected on patients admitted to acute care hospitals. The measure also requires a set of linking variables that are present in both the EHR and claims data, which allows us to match each patient's core clinical data elements to the claim for the relevant admission. We refer readers to the methodology report available on the CMS website for the list of linking variables and more detailed discussion.

(4) Outcome

The outcome of interest for the Hybrid HWM measure is all-cause 30-day mortality. We define all-cause mortality as death from any cause within 30 days of the index hospital admission date.

(5) Cohort

The Hybrid HWM measure cohort consists of Medicare FFS beneficiaries, aged between 65 and 94 years, discharged from a non-Federal, short-term acute care hospital, within the 1-year measurement period (July 1 to June 30 of each year). The measure was developed using ICD–9 codes, and then re-specified and re-tested using ICD–10 data. The Hybrid HWM measure cohort uses the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) [1095] to group numerous diagnostic and procedural ICD–10 codes into the clinically meaningful categories defined by the AHRQ grouper. We made modifications to these AHRQ CCSs based on risk of mortality, as described in the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[1096] The Hybrid HWM measure uses those CCS categories as part of cohort specification and risk-adjustment, including the 15 service-line risk models.

For the AHRQ CCSs and individual ICD–10–CM codes that define the measure development cohort, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk

[1095] Clinical Classifications Software Refined (CCSR) *https://www.hcup-us.ahrq.gov/toolssoftware/ccsr/ccs_refined.jsp*.

[1096] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

Factors Measure Methodology Report Version 2.0.[1097]

(6) Inclusion and Exclusion Criteria

The Hybrid HWM measure cohort currently includes Medicare FFS patients who—

- Were enrolled in Medicare FFS Part A for the 12 months prior to the date of admission and during the index admission;
- Have not been transferred from another inpatient facility;
- Were admitted for acute care (do not have a principal discharge diagnosis of a psychiatric disease or do not have a principal discharge diagnosis of ''rehabilitation care; fitting of prostheses and adjustment devices'');
- Are between 65 and 94 years of age;
- Are not enrolled in hospice at the time of or in the 12 months prior to their index admission;
- Are not enrolled in hospice within 2 days of admission;
- Are without a principal diagnosis of cancer and enrolled in hospice during their index admission;
- Are without any diagnosis of metastatic cancer; and
- Are without a discharge diagnosis that is present on admission (POA) for a condition for which hospitals have limited ability to influence survival, including: Anoxic brain damage; persistent vegetative state; prion diseases such as Creutzfeldt-Jakob disease, Cheyne-Stokes respiration; brain death; respiratory arrest; or cardiac arrest without a secondary diagnosis of acute myocardial infarction.

The measure currently excludes any of the following index admissions for patients:

- With inconsistent or unknown vital status;
- Discharged against medical advice;
- With an admission for crush injury, burn, intracranial injury, skull and face fractures, open wounds of head, neck, and trunk, or spinal cord injury; or
- With an admission in a low-volume CCS (within a particular service-line division), defined as equal to or less than 100 patients with that principal diagnosis across all hospitals.

The Hybrid HWM measure assigns each index admission to one of the mutually exclusive service-line divisions. For details on how each admission is assigned to a specific service-line division, and for a complete description and rationale of the inclusion and exclusion criteria, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[1098]

(7) Risk Adjustment

The Hybrid HWM measure adjusts for both case mix differences (clinical status of the patient, accounted for by adjusting for age and comorbidities) and service-mix differences (the types of conditions and procedures cared for and procedures conducted by the hospital, accounted for by the discharge CMS condition category and AHRQ CCS). Patient comorbidities are based on inpatient hospital administrative claims during the 12 months prior to and including the index admission derived from ICD–10 codes grouped into the CMS condition categories (CMS–CCs). Risk variable coefficients vary by service-line division. We used version 22[1099] [1100] of the CMS–CC map (for more information about our risk-adjustment model software, we refer readers to the Risk Adjustment page on the CMS website at: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors.html*).

The Hybrid HWM measure also includes the core clinical data elements in the case mix adjustment. The core clinical data elements are values for lab values and vital signs derived from information captured in the EHR during the index admission only, as described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49699). The core clinical data elements are clinical information meant to reflect a patient's clinical status upon arrival to the hospital. The table lists the 10 specific elements used in the proposed Hybrid HWM measure.

[1097] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[1098] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[1099] Pope GC, Ellis RP, Ash AS, et al. Diagnostic cost group hierarchical condition category models for Medicare risk adjustment. Final Report to the Health Care Financing Administration under Contract Number 500–95–048. 2000; *http://www.cms.hhs.gov/Reports/downloads/pope_2000_2.pdf.* Accessed February 25, 2020.

[1100] Pope GC, Kautter J, Ingber MJ, et al. Evaluation of the CMS–HCC Risk Adjustment Model: Final Report. 2011; *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/evaluation_risk_adj_model_2011.pdf.* Accessed February 25, 2020.

Currently Specified Core Clinical Data Element Variables

Data Elements	Units of Measurement	Time Window for First Captured Values
Heart Rate	Beats per minute	0-2 hours
Systolic Blood Pressure	mmHg	0-2 hours
Temperature	Degrees (Fahrenheit or Celsius)	0-2 hours
Oxygen Saturation	Percent	0-2 hours
Hematocrit	Percent	0-24 hours
Platelet	Count	0-24 hours
White Blood Cell Count	10^9 per liter (X10E+09/L)	0-24 hours
Sodium	mmol/L	0-24 hours
Bicarbonate	mmol/L	0-24 hours
Creatinine	mg/dL	0-24 hours

The core clinical data elements utilize EHR data, therefore, using the Measure Authoring Tool (MAT)—a web-based tool that allows the authoring of eCQMs using a standardized data model and Clinical Quality Language (CQL) expressions [1101]—we developed and tested a MAT output and identified value sets for extraction of the core clinical data elements, which are available at the eCQI Resource Center: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*. For more details on how the risk variables in each measure were chosen, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0.[1102]

The proposed Hybrid HWM measure was initially specified to use core clinical data elements that are similar to, but not precisely the same as, those used in the Hybrid Hospital-Wide Readmission Measure (Hybrid HWR measure) with Claims and Electronic Health Record Data measure (NQF #2879), for which we are currently collecting data from hospitals on a voluntary basis through June 30, 2023 (84 FR 42465). Since the Hybrid HWM measure was described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41581 through 41588), we have updated the core clinical data elements for the Hybrid HWM measure to include hematocrit instead of hemoglobin to better align with the Hybrid HWR measure. Hemoglobin and hematocrit values are highly correlated and interchangeable with respect to their impact in the Hybrid HWM measure's risk model. The Pearson correlation coefficients of hemoglobin to hematocrit ranged from 0.88–0.97, depending on service-line division. We believe this alignment will increase the ease of reporting on both measures.

With this update, hospitals would already collect nine of the ten core clinical data elements used in the Hybrid HWM measure for reporting on the Hybrid HWR measure, with platelets being the only additional data element used specifically for the Hybrid HWM measure. For more detail about the core clinical data elements used in the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data measure (NQF #2879), we refer readers to our discussion in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479) and the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors report (available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*).

We would update the measure specifications annually for the measure to incorporate new and revised ICD–10 codes effective October 1 of each year after clinical review as necessary. We would also update and publicly release the MAT output annually as necessary to include any updates to the electronic specifications, which includes value sets for the measure-specific data elements.

(8) Measure Calculation

Index admissions are assigned to one of 15 mutually exclusive service-line divisions consisting of related conditions or procedures. For each service-line division, the standardized mortality ratio (SMR) is calculated as the ratio of the number of ''predicted'' deaths to the number of ''expected'' deaths at a given hospital. In other words, for each hospital, the numerator of the ratio is the number of deaths within 30 days predicted based on the hospital's performance with its observed case mix and service mix, and the denominator is the number of deaths expected based on the nation's performance with that hospital's case mix and service mix. This approach is analogous to a ratio of ''observed'' to

[1101] The Measure Authoring Tool (MAT) is a publicly available, web-based tool for measure developers to create eMeasures. The MAT now operates under the direction of the Centers for Medicare and Medicaid Services. For more information on the MAT, please visit: *www.emeasuretool.cms.gov*.

[1102] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0, available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

''expected'' used in other types of statistical analyses.

A hospital-wide composite SMR is then created by pooling the service-line SMRs for each hospital using an inverse variance-weighted mean. The inverse variance-weighted mean can be interpreted as a weighted average of all SMRs that takes into account the precision of SMRs. To produce the RSMR, the composite SMR is multiplied by the national observed mortality rate. For additional details regarding the measure specifications to calculate the RSMR, we refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors: Measure Methodology Report Version 2.0.[1103]

We also note an important distinguishing factor about hybrid measures as compared to eCQMs: CMS must calculate hybrid measure results to determine hospitals' risk-adjusted rates relative to national rates using data from all reporting hospitals. With a hybrid measure, hospitals submit data extracted from the EHR, and CMS performs the measure calculations and disseminates results.

During development and testing of the Hybrid HWM measure, we demonstrated that the core clinical data elements were feasibly extracted from hospital EHRs. We also demonstrated that the use of the core clinical data elements to risk-adjust the Hybrid HWM measure results in excellent discrimination (as in, the ability to distinguish patients with a low risk of mortality from those at high risk of mortality) of the measure, as assessed by the c-statistic. C-statistics ranged from 0.82 to 0.95, depending on the service line division. The adjusted intraclass correlation coefficient (ICC), which assesses reliability of the RSMR, also demonstrated high reliability at 0.7748.[1104]

(9) Data Submission

(a) Reporting and Submission Timeframes for Proposed Voluntary and Mandatory Reporting Periods

For this measure, we would start with voluntary reporting in response to the MAP recommendation before requiring data submission. We believe that taking an incremental approach to implementing this proposed measure would allow hospitals more time to update and validate their systems, to ensure data mapping is accurate and complete, to implement workflow changes as necessary to better prepare for submitting data, and to increase familiarity with data submission for hybrid quality measures when the Hybrid HWM measure becomes required. We are proposing a stepwise approach in which we would first accept data submissions for the Hybrid HWM measure during a voluntary reporting period. In this period, we would collect data on the Hybrid HWM measure in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules (45 CFR parts 160 and 164, Subparts A, C, and E), and other applicable law. This voluntary reporting period would include four quarters of data. Specifically, the voluntary reporting period would run from July 1, 2022 through June 30, 2023. Hospitals that elect to submit data should do so according to the requirements described in this section and in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58940 through 58942). Under previously established policy, hospitals must submit the core clinical data elements and linking variables within 3 months following the end of the applicable reporting period (submissions would be required no later than the first business day 3 months following the end of the reporting period).

We are proposing that mandatory reporting would begin with the reporting period which runs from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years. Hospitals would be required to submit the core clinical data elements and linking variables within 3 months following the end of the applicable reporting period (submissions would be required no later than the first business day 3 months following the end of the reporting period). This proposed mandatory reporting period for the Hybrid HWM measure aligns with that of the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) that was finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479).

Notably, while we finalized two voluntary reporting periods for the Hybrid Hospital-Wide Readmission measure (84 FR 42465 through 42479), here, we are only proposing to have one voluntary reporting period for the Hybrid HWM measure, which would coincide with the second voluntary reporting period for the Hybrid Hospital-Wide Readmission measure. We believe one voluntary reporting period is sufficient for the Hybrid HWM measure because hospitals will already have two separate opportunities to learn how to report the core clinical data elements for the Hybrid Hospital-Wide Readmission measure, which mostly align with the Hybrid HWM measure core clinical data elements as described previously. Therefore, hospitals would have the opportunity to familiarize themselves with the reporting requirements and process for the core clinical data elements prior to the Hybrid HWM measure voluntary reporting period.

(b) File Type

Beginning with the proposed voluntary reporting period using data from July 1, 2022 through June 30, 2023, we are proposing that hospitals would use Quality Reporting Data Architecture (QRDA) Category I files for each Medicare FFS beneficiary aged between 65 and 94 years. Submission of data to CMS using QRDA I files is the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program (84 FR 42506, 85 FR 58940). This same standard would be used for reporting the core clinical data elements to the CMS data receiving system via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Specifically, to successfully submit the Hybrid HWM measure, hospitals would need to submit the core clinical data elements included in the Hybrid HWM measure, as described in the measure specifications, for all Medicare FFS beneficiaries aged between 65 and 94 years discharged from an acute care hospitalization in the 1-year measurement period (July 1 to June 30 of each year). We note this aligns with the measurement period for the Hybrid HWR measure (84 FR 42465 through 42479).

(c) Data Thresholds

For us to be able to calculate the Hybrid HWM measure results, each hospital would need to report vital signs for 90 percent or more of the hospital admissions for Medicare FFS patients, aged between 65 and 94 years old discharged in the measurement period (as determined from the claims submitted to CMS for admissions that ended during the same reporting period). Vital signs are measured on nearly every adult patient admitted to an acute care hospital and should be

[1103] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Measure Methodology Report Version 2.0. Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[1104] Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics.* 1977:159–174.

present for nearly 100 percent of discharges (identified in Medicare FFS claims submitted during the same period). In addition, calculating the measure with more than 10 percent of hospital discharges missing these data elements could cause poor reliability of the measure score and instability of hospitals' results from measurement period to measurement period.

Hospitals would also need to report the laboratory test results for 90 percent or more of hospital admissions for nonsurgical patients, meaning those not included in the surgical divisions of the Hybrid HWM measure. For many patients in the surgical divisions admitted following elective surgery, there are no laboratory values available in the appropriate time window. Therefore, there is no submission requirement for the surgical divisions. However, hospitals should submit lab values for those patients in surgical divisions with lab values available within the appropriate time window. Laboratory values submitted would be included in the risk adjustment model.

(d) Linking Variables and Other Data Elements

Hospitals would also be required to successfully submit the following six linking variables that are necessary in order to merge the core clinical data elements with the CMS claims data to calculate the measure:

- CMS Certification Number;
- Health Insurance Claims Number or Medicare Beneficiary Identifier;
- Date of birth;
- Sex;
- Admission date; and
- Discharge date.

The six linking variables required for linking EHR and claims data should be routinely captured and available for nearly every adult patient admitted to an acute care hospital.

Because these linking variables are required for billing, they should be present for all Medicare FFS patients, and are, therefore, ideally suited to support merging claims and EHR data. However, hospitals would meet Hospital IQR Program requirements if they submit linking variables on 95 percent or more of discharges with a Medicare FFS claim for the same hospitalization during the measurement period.

(10) Public Reporting

(a) Proposed Voluntary Reporting Period

Under this proposal, we would not publicly report data collected during the voluntary reporting period. Hospitals that submit data for this measure during the voluntary reporting period would receive confidential hospital-specific reports that detail submission results from the applicable reporting period, as well as the Hybrid HWM measure results assessed from merged files created by our merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admissions. Hospitals voluntarily reporting would receive information and instructions on the use of the electronic specifications for this measure, have an opportunity to test extraction and submission of data to CMS, and receive feedback reports from CMS, available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System), with details on the success.

(b) Mandatory Reporting

We are proposing mandatory data submission, including public reporting of the Hybrid HWM measure, beginning with the data from the July 1, 2023 through June 30, 2024 reporting period, affecting the FY 2026 payment determination and for subsequent years. We anticipate this data would be included in the July 2025 refresh of the *Care Compare* website or its successor website.

The EHR data would be merged with the associated claims data, and then Hybrid HWM measure results would be shared with hospitals in the confidential hospital-specific feedback reports planned for the spring of 2025, providing hospitals a 30-day review period prior to public reporting. Thereafter, in subsequent reporting years, we would follow a similar operational timeline for EHR data submissions, availability of hospital specific reports, and public reporting on the *Care Compare website* or its successor website.

We refer readers to section IX.C.8.f. of the preamble of this proposed rule for more details and proposals related to data submission requirements for hybrid measures, including the Hybrid HWM measure.

We invite public comment on our proposal to adopt the Hybrid Hospital-Wide Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) (Hybrid HWM measure) into the Hospital IQR Program, beginning with voluntary reporting period which would run from July 1, 2022 through June 30, 2023, followed by mandatory reporting beginning with the reporting period which runs July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination, and subsequent years.

c. Proposal To Adopt the COVID–19 Vaccination Coverage Among HCP Measure Beginning With Shortened Reporting Period From October 1, 2021 Through December 31, 2021, Affecting the CY 2021 Reporting Period/FY 2023 Payment Determination and for Subsequent Years

(1) Background

On January 31, 2020, the Secretary of the U.S. Department Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[1105] COVID–19 is a contagious respiratory infection [1106] that can cause serious illness and death. Older individuals and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[1107]

As of April 2, 2021 the U.S. reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[1108] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[1109] From December 2, 2020 through January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[1110]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[1111]

[1105] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[1106] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[1107] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[1108] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[1109] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[1110] US Currently Hospitalized | The COVID Tracking Project. Accessed January 31, 2021 at: *https://covidtracking.com/data/charts/us-currently-hospitalized*.

[1111] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April

Continued

The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[1112] Thus, the Centers for Disease Control and Prevention advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[1113] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface (although that is not thought to be a common way that COVID–19 spreads),[1114] and that in certain circumstances, infection can occur through airborne transmission.[1115] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[1116] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between health care personnel (HCP) and patients, or from patient to patient given the close contact that may occur during the provision of care.[1117] The CDC has emphasized that health care settings, including long-term care settings, can be high-risk places for COVID–19 exposure and transmission.[1118]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately helps restore societal functioning.[1119] On December 11, 2020, the FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[1120] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[1121]

The FDA determined that the vaccines met the statutory criteria for issuance of an EUA. The totality of the available data provided clear evidence that the vaccines may be effective to prevent COVID–19, and that the known and potential benefits of the vaccines, when used as authorized to prevent COVID–19, outweighed the known and potential risks.[1122]

As part of its national strategy to address COVID–19, the Biden Administration stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[1123] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[1124] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccine given the potential for transmission in health care settings and the need to preserve health care system capacity.[1125] Research suggests most states followed this recommendation,[1126] and HCP began receiving the vaccine in mid-December of 2020.[1127]

Frontline healthcare workers, such as those employed in acute care hospitals, are being prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the United States.[1128] As of April 3, 2021, the CDC reported that over 162 million doses of the COVID–19 vaccine had been administered, and approximately 60 million people had received a complete vaccination course.[1129] President Biden indicated on April 6, 2021 that the United States has

3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1112] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1113] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1114] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1115] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1116] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html.*

[1117] Centers for Disease Control and Prevention. (2021). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission.*

[1118] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[1119] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[1120] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144412/download.*

[1121] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*; U.S. Food and Drug Administration. (2020). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*; U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

[1122] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144412/download* Tech COVID–19 Vaccine EUA Letter of Authorization (fda.gov); U.S. Food and Drug Administration. (2020). ModernaTx, Inc. COVID–19 Vaccine EUA Letter of Authorization. *Available* at: *https://www.fda.gov/media/144636/download*; U.S. Food and Drug Administration. (January 2020). Guidance Document: Emergency Use Authorization of Medical Products and Related Authorities. Accessed on December 17, 2020, at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#scope.*

[1123] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[1124] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[1125] Dooling, K, McClung, M, and et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[1126] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

[1127] Associated Press. 'Healing is Coming:' U.S. Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[1128] CDC/The National Institute for Occupational Safety and Health (NIOSH). Health Care Workers. Accessed on February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html#:~:text=HEALTHCARE%20WORKERS,-Related%20Pages&text=Healthcare%20is%20the%20fastest%2Dgrowing,of%20the%20healthcare%20work%20force.*

[1129] CDC. COVID Data Tracker. COVID–19 Vaccinations in the United States. Accessed on 2/18/21 at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations.*

sufficient vaccine supply to make every adult eligible to receive a vaccine beginning April 19, 2021.[1130]

We believe it is important to incentivize and track HCP vaccination in acute care facilities through quality measurement to protect health care workers, patients, and caregivers, and to help sustain the ability of hospitals to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing a new measure, COVID–19 Vaccination Coverage Among HCP, beginning with a shortened reporting period from October 2021 through December 2021. The CY 2021 Reporting Period for the FY 2023 Payment Determination is shorter than the reporting period we are proposing for subsequent years to expedite data collection of this measure in response to the current PHE. The measure will assess the proportion of a hospital's health care workforce that has been vaccinated against COVID–19.

Although at this time data to show the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS–CoV–2 are limited, we believe hospitals should track the level of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19 within their facilities. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[1131] Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients,[1132] and we believe HCP COVID–19 vaccination in hospitals could similarly increase uptake among that patient population.

We also believe that publishing the HCP vaccination rates will be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 measure addresses the quality priority of ''Promoting Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as acute care facilities.

(a) Measure Specifications

The denominator is the number of HCP eligible to work in the healthcare facility for at least one day during the submission period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[1133]

The numerator is the cumulative number of HCP eligible to work in the health care facility for at least one day during the submission period and who received a completed vaccination course against COVID–19 since the date the vaccine was first available or on a repeated interval if revaccination is recommended.[1134] Vaccination coverage for the purposes of this measure is defined as the estimated percentage of HCP eligible to work at the IPF for at least one day who received a completed vaccination course. A completed vaccination course may require one or more doses depending on the EUA for the specific vaccine used. We refer readers to *https://www.cdc.gov/nhsn/nqf/index.html* for more details on the measure specifications.

(b) Review by the Measure Applications Partnership (MAP)

The COVID–19 Vaccination Coverage Among HCP measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List), a list of measures under consideration for use in various Medicare programs.[1135] When the MAP Hospital Workgroup convened on January 11, 2021, it reviewed the measures on the MUC List, including the COVID–19 HCP vaccination measure.[1136] The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the Hospital IQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[1137] The MAP also stated that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[1138]

In its preliminary review, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[1139] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[1140] Subsequently, the MAP Coordinating Committee met on January 25, 2021, to review and make a recommendation on the COVID–19 Vaccination Coverage Among HCP measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications are further refined specifically saying that ''the incomplete specifications require immediate mitigation and further development should continue.'' [1141] In its final report, the MAP noted that the measure would

[1130] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/.*

[1131] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm.*

[1132] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1133] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications.*

[1134] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx.*

[1135] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

[1136] The MUC List and the MAP referred to the measure as the ''SARS–CoV–2 Vaccination Coverage Among Healthcare Personnel.''

[1137] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[1138] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[1139] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[1140] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

[1141] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 23, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx.*

add value to the program measure set by providing visibility into an important intervention to limit COVID–19 infections in healthcare personnel and the patients for whom they provide care.[1142] The spreadsheet of final recommendations no longer cited concerns regarding evidence, testing, or NQF endorsement.[1143]

In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with MAP Coordinating committee on March 15, 2021. CMS and the CDC provided additional information to the MAP Coordinating Committee at that meeting to address vaccine availability, the alignment of the COVID–19 Vaccination Coverage Among HCP as closely as possible with the Influenza HCP vaccination measure (NQF 0431) specifications, and the definition of HCP used in the measure. At this meeting, CMS and the CDC also presented preliminary findings from the testing of the numerator of COVID–19 Vaccination Coverage Among HCP, which is currently in process. These preliminary findings showed that the numerator data should be feasible and reliable. Testing of the numerator of the number of healthcare personnel vaccinated involves a comparison vaccination data collected by the CDC directly from long-term care facilities (LTCFs) through NHSN with vaccination data independently reported to the CDC through the Federal pharmacy partnership program for delivering vaccination to LTC facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination from December 2020 to January 2021, the number of healthcare workers vaccinated in approximately 1,200 facilities, which had data from both systems the number of healthcare personnel vaccinated was highly correlated between these 2 systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[1144] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least one dose of the COVID–19 vaccine, we believe this data indicates the measure is feasible and reliable for use in the IQR Program.

We value the recommendations of the MAP and considered these recommendations carefully. Section 1890A(a)(4) of the Act, as added by section 3014(b) of the Affordable Care Act, requires the Secretary to take into consideration input from multi-stakeholder groups in selecting quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on vulnerable populations. CMS continues to engage with the MAP to mitigate concerns and appreciates the MAP's conditional support for the measure.

(3) NQF Endorsement

Under section 1886(s)(4)(D)(i) of the Act, unless the exception of subclause (ii) applies, measures selected for the quality reporting program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The NQF currently holds this contract. Section 1886(s)(4)(D)(ii) of the Act provides an exception to the requirement for NQF endorsement of measures: In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

This measure is not NQF-endorsed and has not been submitted to NQF for endorsement consideration. CMS will consider the potential for future NQF endorsement as part of its ongoing work with the MAP.

Because this measure is not NQF-endorsed, we considered other available measures. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore we believe the exception in section 1186(s)(4)(D)(ii) of the Act applies.

(4) Data Submission and Reporting

Given the time-sensitive nature of this measure in light of the PHE, we are proposing that for the FY 2023 program year, the reporting period would be from October 1, 2021 through December 31, 2021. The reporting period we are proposing is shorter than the reporting period for subsequent years to expedite data collection for this measure in order to respond to the current PHE. Thereafter, we propose quarterly reporting deadlines for the Hospital IQR Program beginning with the CY 2022 reporting period/FY 2024 payment determination and for subsequent years.

To report this measure, we are proposing that hospitals would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital IQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that hospitals would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a hospital's healthcare personnel while balancing the costs of reporting. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IX.C.10.c.2.a., hospitals would report the number of HCP eligible to have worked at the facility during the self-selected week that the hospital reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

We invite public comment on our proposal to add a new measure, COVID–

[1142] Measure Applications Partnership. 2020–2021 Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on March 12, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1143] Measure Applications Partnership. 2020–2021 MAP Final Recommendations. Accessed on February 18 at: NQF: Measure Applications Partnership (*qualityforum.org*).

[1144] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

19 Vaccination Coverage Among HCP, to the Hospital IQR Program, beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 for the FY 2023 payment determination, and continuing with quarterly reporting deadlines for the CY 2022 reporting period/FY 2024 payment determination and for subsequent years.

d. Proposal To Adopt Two Medication-Related Adverse Event Electronic Clinical Quality Measures Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

In this proposed rule, we are proposing to add two new medication-related adverse event electronic clinical quality measures (eCQMs) to the Hospital IQR Program measure set, beginning with the CY 2023 reporting period/FY 2025 payment determination: (1) Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e); and (2) Hospital Harm—Severe Hyperglycemia eCQM (NQF#3533e). We believe these medication-related adverse event measures are valuable patient safety measures and focus on high-priority measurement areas and patient outcomes. The measures were developed in a manner that allows them to be reported independently, but they can be considered balancing measures if a hospital chooses to report on both measures. This section includes additional details on each of the eCQMs.

(1) Proposed Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e) Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

(a) Background

Hypoglycemia is defined as a blood glucose level of less than or equal to 70 mg/dl.[1145] Hypoglycemic events are among the most common adverse drug events in hospitals.[1146] [1147] [1148] [1149] Hypoglycemia can cause a wide range of symptoms, including mild symptoms of dizziness, sweating, and confusion to more severe symptoms such as seizure, tachycardia, or loss of consciousness.[1150] [1151] Most individuals with hypoglycemia recover fully, but in rare instances, hypoglycemia can progress to coma and death.[1152]

In a study examining clinical outcomes associated with hypoglycemia in hospitalized people with diabetes, patients who had at least one hypoglycemic episode (a blood glucose level of less than 50 mg/dL) were hospitalized 2.8 days longer than patients who did not experience hypoglycemia.[1153] Another retrospective cohort study showed hospitalized patients with diabetes who experienced hypoglycemia (a blood glucose level of less than 70 mg/dL) had higher medical costs (by 38.9 percent), longer length of stay (by 3.0 days), and higher odds of being discharged to a skilled nursing facility (odds ratio 1.58; 95 percent Confidence Interval 1.48–1.69) than patients with diabetes without hypoglycemia ($p<0.01$ for all).[1154] Hypoglycemia is associated with higher in-hospital mortality, increased length of stay, and consequently, increased resource utilization.[1155]

The rate of severe hypoglycemia (a blood glucose level of less than 40 mg/dL) varies across hospitals, indicating an opportunity for improvement in care.[1156] [1157] [1158] [1159] Severe hypoglycemia rates have been reported to range from 2.3–5 percent of hospitalized patients with diabetes, and from 0.4 percent of non-ICU patient days to 1.9 percent of ICU patient days.[1160] [1161] [1162] Severe hypoglycemic events are largely avoidable by careful use of anti-diabetic medication and close monitoring of blood glucose values.[1163] [1164] [1165]

Although there are many occurrences of hypoglycemia in hospital settings and many such events are preventable, there is currently no measure in a CMS quality program that quantifies how often hypoglycemic events happen to patients while in inpatient acute care. The AHRQ identified insulin and other hypoglycemic agents as high-alert medications and associated adverse drug events to be included as a measure in the Medicare Patient Safety Monitoring System (MPSMS), signifying the importance of measuring this hospital harm.[1166] [1167] Unlike the

[1145] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1146] Lipska KJ, Ross JS, Wang Y, et al. National trends in US hospital admissions for hyperglycemia and hypoglycemia among medicare beneficiaries, 1999 to 2011. JAMA Intern Med. 2014; 174(7):1116–1124. doi:10.1001/jamainternmed.2014.1824.

[1147] McCoy RG, Lipska KJ, Herrin J, Jeffery MM, Krumholz HM, Shah ND. Hospital Readmissions among Commercially Insured and Medicare Advantage Beneficiaries with Diabetes and the Impact of Severe Hypoglycemic and Hyperglycemic Events. J Gen Intern Med. 2017; 32(10):1097–1105. doi:10.1007/s11606–017–4095-x.

[1148] Office of the Inspector General (OIG). (2010). Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Available at: *https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf*.

[1149] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. Diabetes Care, 30(2): 367–369.

[1150] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1151] Turchin, A., Matheny, M.E., Shubina, M., Scanlon, J.V., Greenwood, B., & Pendergrass, M.L. (2009). Hypoglycemia and clinical outcomes in patients with diabetes hospitalized in the general ward. Diabetes Care, 32(7): 1153–57.

[1152] Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin dependent diabetes mellitus. New England Journal of Medicine, 329(14): 977–86.

[1153] Turchin, A., Matheny, M.E., Shubina, M., Scanlon, J.V., Greenwood, B., & Pendergrass, M.L. (2009). Hypoglycemia and clinical outcomes in patients with diabetes hospitalized in the general ward. Diabetes Care, 32(7): 1153–57.

[1154] Curkendall, S.M., Natoli, J.L., Alexander, C.M., Nathanson, B.H., Haidar, T., & Dubois, R.W. (2009). Economic and clinical impact of inpatient diabetic hypoglycemia. Endocrine Practice, 15(4): 302–312.

[1155] Krinsley, J.S., Schultz, M.J., Spronk, P.E., van Braam Houckgeest, F., van der Sluijs, J.P., Melot, C. & Preiser, J.C. (2011). Mild hypoglycemia is strongly associated with increased intensive care unit length of stay. Ann Intensive Care, 1, 49.

[1156] Hospital Harm—Severe Hypoglycemia (NQF #3503e) Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3503*.

[1157] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1158] Egi M, Bellomo R, Stachowski E, et al. Hypoglycemia and outcome in critically ill patients. Mayo Clin Proc. 2010; 85(3):217–224. doi:10.4065/mcp.2009.0394.

[1159] Krinsley JS, Grover A. Severe hypoglycemia in critically ill patients: risk factors and outcomes. Crit Care Med. 2007 Oct; 35(10):2262–7.

[1160] Nirantharakumar, K., Marshall, T., Kennedy, A., Narendran, P., Hemming, K., & Coleman, J.J. (2012). Hypoglycemia is associated with increased length of stay and mortality in people with diabetes who are hospitalized. Diabetic Medicine, 29(12): e445–e448.

[1161] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. Diabetes Care, 30(2): 367–369.

[1162] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1163] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1164] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012; 97(1):16–38.

[1165] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1166] Classen, DC, Jaser, L., Budnitz, D.S. (2010). Adverse Drug Events among Hospitalized Medicare Patients: Epidemiology and national estimates from

Continued

MPSMS, which relies on chart-abstracted data, the Hospital Harm—Severe Hypoglycemia eCQM identifies hypoglycemic events using direct extraction of structured data from the EHR. In addition, the National Action Plan for Adverse Drug Event Prevention highlighted the opportunity that exists for healthcare quality reporting measures and meaningful utilization of EHR data to advance prevention of hypoglycemic adverse drug events.[1168]

To address gaps in measurement, we developed the Hospital Harm—Severe Hypoglycemia eCQM, an outcome measure that would identify the rates of severe hypoglycemic events using direct extraction of structured data from the EHR. We believe this measure will provide reliable and timely measurement of the rate at which severe hypoglycemia events occur in the setting of hospital administration of antihyperglycemic medications during hospitalization, which will create transparency for providers and patients with respect to variation in rates of these events among hospitals. We believe that adopting this measure, which focuses on in-hospital severe hypoglycemic events in the setting of hospital-administered antihyperglycemic medications, has the potential to reduce preventable harm. Therefore, we are proposing to adopt the Hospital Harm—Severe Hypoglycemia eCQM (NQF #3503e) beginning with the CY 2023 reporting period/FY 2025 payment determination.

(b) Overview of Measure

The Hospital Harm—Severe Hypoglycemia eCQM identifies the proportion of patients who experienced a severe hypoglycemic event, defined as a glucose test result of less than 40 mg/dL, within 24 hours of the administration of an antihyperglycemic agent, which indicates harm to a patient.[1169] The measure is intended to facilitate safer patient care, not only by promoting adherence to recommended clinical guidelines, but also by incentivizing hospitals to track and improve their practices of appropriate dosing and adequate monitoring of patients receiving glycemic control agents. Hospitals could use this measure to track and improve their practices of appropriate dosing and adequate monitoring of patients receiving glycemic control agents, and to avoid patient harm that can lead to increased risk of mortality and disability. This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measure Area of ''Preventable Healthcare Harm.'' [1170]

This measure is a re-specification of another hypoglycemia measure originally endorsed by the NQF, Glycemic Control—Hypoglycemia (NQF #2363).[1171] The original measure was not implemented as an eCQM because, at that time, limitations in the MAT did not allow for accurate expression of the Quality Data Model (QDM) components to express the measure logic or syntax as specified.[1172] Upgrades to the MAT have allowed the measure to be re-specified, producing accurate expression of the measure logic in CQL format to create a measure that can now be implemented.

The Hospital Harm—Severe Hypoglycemia (MUC18–109) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2018.'' [1173] This measure was reviewed by the NQF MAP Hospital Workgroup in December 2018 and received conditional support pending NQF review and re-endorsement once the revised measure is fully tested.[1174] [1175] MAP stakeholders expressed concerns about the low glucose value (less than 40 mg/dL), the defined lab tests (for example, point-of-care vs. lab values), and the feasibility of the subsequent lab test for glucose within 5 minutes of the low glucose result. MAP stakeholders agreed that severe hypoglycemia events are largely avoidable by careful use of antihyperglycemic medications and blood glucose monitoring. The MAP recommended continuously assessing the low blood glucose threshold of <40mg/dL for defining harm events to assess unintended consequences.[1176] The MAP Coordinating Committee, which provides direction to the MAP workgroups, concurred with the recommendations of the MAP Hospital Workgroup. The measure was fully tested in six hospitals with two different EHR vendors (Epic and Cerner) at thresholds found to be feasible, reliable, valid, and scientifically acceptable by the NQF Patient Safety Standing Committee and was subsequently endorsed by the NQF Consensus Standards Advisory Committee (CSAC) in the Spring of 2019.[1177] [1178]

(c) Data Sources

The proposed measure is an eCQM that uses data collected through the EHR. The measure is designed to be calculated by the hospitals' certified electronic health record technology (CEHRT) using the patient-level data submitted by hospitals to CMS.

(d) Measure Calculation

The Hospital Harm—Severe Hypoglycemia eCQM is an outcome measure that assesses the rate at which severe hypoglycemia events (blood glucose test result less than 40 mg/dL) caused by hospital administration of medications occur in the acute care hospital setting. The measure calculates the proportion of patients who are at risk and who had a low blood glucose test result (less than 40 mg/dL) and no subsequent confirmatory blood glucose within 5 minutes and in the normal range (greater than 80 mg/dL). Patients at risk include those who had an antihyperglycemic medication administered in the hospital within the 24 hours prior to the harm event. The measure counts only one severe hypoglycemia event per patient

a new approach to surveillance. Joint Commission Journal on Quality and Patient Safety, 36(1): 12–21.

[1167] New System Aims To Improve Patient Safety Monitoring. Content last reviewed October 2016. Agency for Healthcare Research and Quality, Rockville, MD. Available at: *https://archive.ahrq.gov/news/blog/ahrqviews/new-system-aims-to-improve-patient-safety-monitoring.html*.

[1168] Office of Disease Prevention and Health Promotion. (2014). National Action Plan for Adverse Drug Event Prevention. Available at: *https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf*.

[1169] Hospital Harm—Severe Hypoglycemia (NQF #3503e). Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3503*.

[1170] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page*.

[1171] Glycemic Control—Hyperglycemia NQF#2363. Available at: *http://www.qualityforum.org/QPS/2363e*.

[1172] Hospital Harm—Severe Hypoglycemia (NQF #3503e) Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3503*.

[1173] Measures Under Consideration List December 1, 2018. Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88812*.

[1174] 2018–2019 Spreadsheet of Final Recommendations to HHS and CMS. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[1175] National Quality Forum, Measure Applications Partnership, MAP 2019 Considerations for Implementing Measures in Federal Programs: Hospitals. Available at: *http://www.qualityforum.org/Publications/2019/02/MAP_2019_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx*.

[1176] Measure Applications Partnership, December 2018 NQF MAP Hospital Workgroup Preliminary Recommendations. Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75369*.

[1177] NQF October 2019 CSAC Endorsement. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91440*.

[1178] NQF Patient Safety Standing Committee Memo to Consensus Standards Advisory Committee. Spring 2019 Cycle. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91278*.

admission. We refer readers to the measure specifications for more detail: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

(e) Measure Cohort

The measure's cohort includes all patients ages 18 years and older at the start of the encounter, and for whom at least one antihyperglycemic medication was administered during the encounter.

(f) Denominator

The measure denominator includes all patients 18 years or older discharged from an inpatient hospital encounter during the measurement period who were administered at least one antihyperglycemic medication during their hospital stay. The measure includes inpatient admissions for patients admitted from either the emergency department or observation status, who subsequently became an inpatient. There are no denominator exclusions for this measure.

(g) Numerator

The numerator for this measure is the number of hospitalized patients with a blood glucose test result of less than 40 mg/dL (indicating severe hypoglycemia) with no repeat glucose test result greater than 80 mg/dL within 5 minutes of the initial low glucose test, and where an antihyperglycemic medication was administered within 24 hours prior to the low glucose result. We specified a glucose threshold of less than 40 mg/dL to identify only cases of severe hypoglycemia. We excluded a single severe hypoglycemic event with a repeat test of over 80 mg/dL within 5 minutes to avoid counting false positives (for example, from bedside point-of-care tests of capillary blood that might have returned an initial erroneous result). There are no other numerator exclusions for this measure.

(h) Risk Adjustment

We note risk adjustment is not applicable to the Hospital Harm-Severe Hypoglycemia eCQM. In the case of the Hospital Harm—Severe Hypoglycemia eCQM, there is evidence indicating that most hypoglycemic events of this severity (<40 mg/dL) are avoidable.[1179] [1180] [1181] [1182] Although specific patients may be particularly vulnerable to hypoglycemia in certain settings (for example, due to organ failure and not related to administration of diabetic agents), the most common causes are lack of caloric intake, overuse of anti-diabetic agents, or both.[1183] [1184] [1185] These causes are largely controllable in hospital environments, and risk can be reduced by following best practices. We would continue to evaluate the appropriateness of risk adjustment in measure reevaluation.

For more information on the Hospital Harm—Severe Hypoglycemia eCQM, we refer readers to the measure specifications available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

We invite public comment on our proposal to adopt the Hospital Harm—Severe Hypoglycemia eCQM for the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.C.5.d.1. of the preamble of this proposed rule for a similar proposal to adopt this eCQM under the Medicare Promoting Interoperability Program. We also refer readers to section IX.C.8.e.2. of the preamble of this proposed rule for additional proposals related to eCQM certification requirements under the Hospital IQR Program.

(2) Proposed Hospital Harm—Severe Hyperglycemia eCQM (NQF # 3533e) Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

(a) Background

Hyperglycemia is common among hospitalized patients, especially those with preexisting diabetes.[1186] [1187] Hyperglycemia can also affect individuals with no prior history of diabetes and may be induced by medications such as steroids, or parenteral (intravenous) or enteral (tube) feeding.[1188] Severe hyperglycemia, or an extremely elevated blood glucose level, is associated with a range of harms, including increased in-hospital mortality, infection rates, and hospital length of stay.[1189] [1190] [1191] [1192] [1193] [1194] [1195] [1196] [1197] The rate of severe hyperglycemia varies across hospitals, which suggests there are opportunities for improvement in inpatient glycemic management.[1198] [1199] Rates of inpatient

[1179] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

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[1181] Office of the Inspector General (OIG). (2010). Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries. Available at: *https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf*.

[1182] Wexler, D.J., Meigs, J.B., Cagliero, E., Nathan, D.M., & Grant, R.W. (2007). Prevalence of hyper and hypoglycemia among inpatients with diabetes: A national survey of 44 U.S. hospitals. Diabetes Care, 30(2): 367–369.

[1183] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1184] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015;21(4):355–367.

[1185] Milligan PE, Bocox MC, Pratt E, Hoehner CM, Krettek JE, Dunagan WC. Multifaceted approach to reducing occurrence of severe hypoglycemia in a large healthcare system. Am J Health Syst Pharm 2015;72:1631–1641.

[1186] Swanson CM, Potter DJ, Kongable GL, Cook CB. Update on Inpatient Glycemic Control in Hospitals in the United States. Endocr Pract. 2011; 17(6):853–861.

[1187] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1188] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

[1189] American Diabetes Association. Diabetes Care in the Hospital: Standards of Medical Care in Diabetes—2018. Diabetes Care 2018; 41(Suppl. 1):S144–S151 (available at: *https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S144.full.pdf*).

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[1193] Lee LJ, Emons MF, Martin SA, et al. Association of Blood Glucose Levels with In-Hospital Mortality and 30-Day Readmission in Patients Undergoing Invasive Cardiovascular Surgery. Curr Med Res Opin. 2012; 28(10):1657–1665.

[1194] King JT, Jr., Goulet JL, Perkal MF, Rosenthal RA. Glycemic Control and Infections in Patients with Diabetes Undergoing Noncardiac Surgery. Ann Surg. 2011; 253(1):158–165.

[1195] Jackson RS, Amdur RL, White JC, Macsata RA. Hyperglycemia is Associated with Increased Risk of Morbidity and Mortality after Colectomy for Cancer. J Am Coll Surg. 2012; 214(1):68–80.

[1196] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012; 97(1):16–38.

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[1198] Swanson CM, Potter DJ, Kongable GL, Cook CB. Update on Inpatient Glycemic Control in Hospitals in the United States. Endocr Pract. 2011; 17(6):853–861.

[1199] Cook, C.B., Kongable, G.L., Potter, D.J., Abad, V.J., Leija, D.E., & Anderson, M. (2009). Inpatient

Continued

severe hyperglycemic events can be considered an indicator for quality of hospital care, since inpatient hyperglycemia is largely avoidable with proper glycemic management.[1200] [1201] [1202] The use of evidence-based standardized protocols and insulin management protocols have been shown to improve glycemic control and safety.[1203] [1204] It should be noted that this measure does not aim to measure overall glucose control in hospitalized patients; rather, our goal is to assess the occurrence and extent of severe hyperglycemia.

(b) Overview of Measure

The intent of this measure is to track and improve practices of appropriate glycemic control and medication management of patients, and to avoid patient harm leading to increased risk of mortality and disability. This eCQM assesses the number of inpatient hospital days with a severe hyperglycemic event among the total qualifying hospital days for patients 18 years and older who have a diagnosis of diabetes mellitus and who either received at least one anti-diabetic medication during the hospital admission, or who had an elevated blood glucose level (>200 mg/dL) during their hospital admission. A severe hyperglycemic event is defined as a day in which a patient's blood glucose result was greater than 300 mg/dL, or a day in which a blood glucose value was not documented and was preceded by 2 consecutive days during which at least one glucose value was 200 mg/dL or greater.[1205] This measure addresses the quality priority of ''Making Care Safer by Reducing Harm Caused in the Delivery of Care'' through the Meaningful Measure Area of ''Preventable Healthcare Harm.''[1206]

The Hospital Harm—Severe Hyperglycemia in Hospitalized Patients (Hospital Harm—Severe Hyperglycemia) (MUC2019–26) measure was included in the publicly available ''List of Measures Under Consideration for December 1, 2019.'' [1207] The MAP Hospital Workgroup reviewed the measure in December 2019 and the MAP Coordinating Committee reviewed the measure in January 2020. The measure received conditional support for rulemaking pending NQF endorsement.[1208] The MAP recommended monitoring the implementation of the measure using the severe high blood glucose threshold of >300mg/dL for defining harm events to assess for unintended measurement consequences, such as hypoglycemia.[1209] The Hospital Harm—Severe Hyperglycemia measure has been found to be both reliable and valid by the NQF Scientific Methods Panel as well as the NQF Patient Safety Standing Committee in the Fall 2019 measure evaluation cycle.[1210] [1211] [1212] As with all quality measures we develop, testing was performed to confirm the measure feasibility, reliability, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing was completed using measure output from the MAT in multiple hospitals, using multiple EHR systems, with the measure shown to be both reliable and valid. In July 2020, the NQF endorsed the Hospital Harm—Severe Hyperglycemia measure.[1213]

This proposed measure is a re-specification of another hyperglycemia measure originally endorsed by the NQF, Glycemic Control—Hyperglycemia (NQF #2362). Similar to the proposed Glycemic Control—Hypoglycemia (NQF #2363) measure, the original hyperglycemic measure was not implemented as an eCQM because, at that time, limitations in the MAT did not allow for accurate expression of the QDM components to express the measure logic or syntax as specified.[1214] [1215] Upgrades to the MAT have allowed the measure to be re-specified, producing accurate expression of the measure logic in CQL format to create a new measure that can now be implemented. We believe that this proposed measure, which focuses specifically on severe hyperglycemic events in the hospital setting, has the potential to reduce preventable harm. Therefore, we are proposing to adopt the Hospital Harm—Severe Hyperglycemia eCQM (NQF # 3533e) beginning with the CY 2023 reporting period/FY 2025 payment determination.

(c) Data Sources

The proposed measure is an eCQM that uses data collected through the EHR. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data submitted by hospitals to CMS.

(d) Measure Calculation

The Hospital Harm—Severe Hyperglycemia eCQM is an outcome measure that assesses the number of hospital days with a severe hyperglycemic event among the total qualifying hospital days for at risk inpatient encounters. A severe hyperglycemic event is defined in the measure as a blood glucose result >300 mg/dL, or a day in which a blood glucose value was not documented, and it was preceded by 2 consecutive days where at least one glucose value was >=200 mg/dL.

(e) Denominator

The denominator of at-risk encounters includes discharges from an inpatient

glucose control: A glycemic survey of 126 U.S. hospitals. Journal of Hospital Medicine, 4(9): E7–E14.

[1200] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1201] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012; 97(1):16–38.

[1202] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006; 15(2):89–91.

[1203] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1204] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006; 15(2):89–91.

[1205] Hospital Harm—Severe Hyperglycemia (NQF #3533e). Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3533.*

[1206] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1207] Measures Under Consideration List December 1, 2019. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91406.*

[1208] 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1209] 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1210] NQF Scientific Methods Panel October 2019 Meeting Summary Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91486.*

[1211] 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1212] NQF Patient Safety Standing Committee. Meeting Summary—Measure Evaluation #1 and #2—Fall 2019 Cycle (Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=92225*) 2019–2020 MAP Final Recommendations. Available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

[1213] Patient Safety Final Report—Fall 2019 Cycle. Available at: *https://www.qualityforum.org/Publications/2020/09/Patient_Safety_Final_Report_-_Fall_2019_Cycle.aspx.*

[1214] Glycemic Control—Hyperglycemia (NQF # 2362e). Available at: *http://www.qualityforum.org/QPS/2362e.*

[1215] Hospital Harm—Severe Hyperglycemia (NQF #3533e). Available at: *http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=3533.*

hospital admission for all patients 18 years and older at the start of the measurement period, as well as—

- A diagnosis of diabetes that starts before or during the encounter;
- Administration of at least one dose of insulin or any anti-diabetic medication during the encounter; or
- Presence of at least one blood glucose value >200 mg/dL at any time during the encounter.

The eCQM includes inpatient encounters which began in the emergency department or in observation status.

The denominator is the total number of eligible days across all encounters that match the initial population criteria. This measure does not count the first 24-hour period after admission to the hospital (including the emergency department) or the last time period before the discharge, if it was less than 24 hours. By excluding the first 24 hours of admission, the measure allows for correction of severe hyperglycemia that was present on admission. By excluding the last time period before discharge if it was less than 24 hours, the measure accounts for the fact that hospitals may not always be able to check glucose during the last time period, especially if it is only a few hours long. Eligible encounters that exceed 10 days are truncated to equal 10 days.

(f) Numerator

The numerator is the total number of hyperglycemic days across all encounters. Hospital days are measured in 24-hour periods, starting from the time of arrival at the hospital (including the emergency department). Days with a hyperglycemic event are defined as either—

- A day with at least one blood glucose value >300 mg/dL; or
- A day in which a blood glucose value was not documented, and it was preceded by 2 consecutive days where at least one glucose value is >=200 mg/dL.

The measure does not count >300 mg/DL events the first 24-hour period after hospital arrival for admitted patients (including the emergency department) or the last time period before discharge, if it was less than 24 hours.

(g) Risk Adjustment

We note risk adjustment is not applicable to the Hospital Harm—Severe Hyperglycemia eCQM. In the case of the Hospital Harm—Severe Hyperglycemia eCQM, there is evidence indicating that most hyperglycemic events of this severity (>300 mg/dL) are avoidable.[1216] [1217] [1218] The rate of inpatient severe hyperglycemia events can be considered a marker for quality of hospital care, since inpatient severe hyperglycemia is largely avoidable with proper glycemic management.[1219] [1220] [1221] We would continue to evaluate the appropriateness of risk adjustment in measure reevaluation.

For more information on the Hospital Harm—Severe Hyperglycemia eCQM, we refer readers to the measure specifications available on the eCQI Resource Center website at: *https://ecqi.healthit.gov/pre-rulemaking-eh-cah-ecqms*.

We invite public comment on our proposal to adopt the Hospital Harm—Severe Hyperglycemia eCQM for the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to section IX.F.5.d.2 of the preamble of this proposed rule for a similar proposal to adopt the Hospital Harm—Severe Hyperglycemia eCQM under the Medicare Promoting Interoperability Program. We also refer readers to section IX.C.8.e.2. of the preamble of this proposed rule for additional proposals related to eCQM certification requirements under the Hospital IQR Program.

6. Proposed Removal of Five Hospital IQR Program Measures

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a discussion of our current measure removal factors. In this proposed rule, we are proposing to remove five measures from the Hospital IQR Program across the FY 2023 and FY 2026 payment determinations as further discussed in this rule.

a. Proposal To Remove One Measure Under—Removal Factor 3, Availability of a More Broadly Applicable Measure (Across Settings, Populations, or the Availability of a Measure That Is More Proximal in Time to Desired Patient Outcomes for the Particular Topic): Death Among Surgical Inpatients With Serious Treatable Complications (CMS PSI–04)

The Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measures in-hospital deaths per 1,000 elective surgical discharges, among 18 through 89 years or obstetric patients with serious treatable complications (shock/cardiac arrest, sepsis, pneumonia, deep vein thrombosis/pulmonary embolism or gastrointestinal hemorrhage/acute ulcer). We refer readers to the FY 2009 IPPS/LTCH PPS final rule where we adopted the Death Among Surgical Patients with Serious Treatable Complications (CMS PSI–04) measure for the FY 2010 payment determination and subsequent years (73 FR 48607) for more detail on this measure. In the FY 2011 IPPS/LTCH PPS final rule, under the RHQDAPU Program (the former title of the Hospital IQR Program), we harmonized two FY 2010 RHQDAPU Program quality measures, combining PSI–04 and ''Nursing Sensitive—Failure to rescue'' into a single measure renamed Death Among Surgical Inpatients with Serious Treatable Complications (75 FR 50182). The CMS PSI–04 measure is a claims-based measure which uses claims and administrative data to calculate the measure without any additional data collection from hospitals.

In this proposed rule, we are proposing to remove this measure beginning with the CY 2021 reporting period/FY 2023 payment determination, because of the availability of a more broadly applicable measure—Factor 3. Specifically, in section IX.C.5.b. of the preamble of this proposed rule, we propose the Hybrid HWM measure (NQF #3502). We refer readers to section IX.C.5.b. for further discussion on the Hybrid HWM measure, including data sources, core clinical data elements, and measure calculation.

The Hybrid HWM measure captures more conditions or procedures than CMS PSI–04. The Hybrid HWM measure also captures mortality within 30 days of hospital admission for most conditions or procedures, compared to deaths for surgical discharges (or pregnancy, childbirth, and puerperium) as measured by CMS PSI–04. While the

[1216] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015; 21(4):355–367.

[1217] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1218] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006;15(2):89–91.

[1219] Maynard G, Kulasa K, Ramos P, et al. Impact of a Hypoglycemia Reduction Bundle and a Systems Approach to Inpatient Glycemic Management. Endocr Pract. 2015;21(4):355–367.

[1220] Umpierrez GE, Hellman R, Korytkowski MT, et al. Management of Hyperglycemia in Hospitalized Patients in Non-Critical Care Setting: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2012;97(1):16–38.

[1221] Donihi AC, DiNardo MM, DeVita MA, Korytkowski MT. Use of a Standardized Protocol to Decrease Medication Errors and Adverse Events Related to Sliding Scale Insulin. Qual Saf Health Care. 2006;15(2):89–91.

CMS PSI–04 measure is claims-based, the Hybrid HWM measure uses a hybrid of claims and clinical data elements from the EHR. As a result, we believe the Hybrid HWM measure is a more broadly applicable measure because it incorporates a much larger set of conditions and procedures and moves toward greater use of EHR data for quality measurement. We note that removal of the CMS PSI–04 measure is contingent on the adoption of the Hybrid HWM measure.

We invite public comment on our proposal to remove the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measure beginning with the FY 2023 payment determination.

b. Proposal To Remove One Measure Under—Removal Factor 5, Availability of a Measure That Is More Strongly Associated With Desired Patient Outcomes for the Particular Topic: Exclusive Breast Milk Feeding (PC–05) (NQF #0480)

The Exclusive Breast Milk Feeding (PC–05) eCQM assesses the number of newborns exclusively fed breast milk during the newborn's entire hospitalization. For more details on the PC–05 measure, we refer readers to the FY 2015 IPPS/LTCH PPS final rule in which we adopted the measure for the Hospital IQR Program (79 FR 50242 through 50243). We are proposing to remove PC–05 beginning with the CY 2024 reporting period/FY 2026 payment determination under Factor 5—the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

Specifically, in keeping with our focus on maternal health, we are proposing to adopt the Maternal Morbidity Structural Measure for inclusion in the Hospital IQR Program beginning with a shortened CY 2021 reporting period/FY 2023 payment determination. We refer readers to section IX.C.5.a. of the preamble of this proposed rule for more detail on that proposed measure. We believe that the proposed Maternal Morbidity structural measure is more strongly aligned with our current focus on maternal health than the PC–05 eCQM. The proposed Maternal Morbidity Structural Measure focuses on determining hospital participation in a State or national Perinatal Quality Improvement (QI) Collaborative initiative and implementation of patient safety practices or bundles within that QI initiative, which includes breastfeeding, while PC–05 targets only breastfeeding, a less holistic area of maternal health. Improving maternal health and the quality of maternal care is a priority for CMS, and we believe that the proposed Maternal Morbidity Structural Measure will help achieve this desired outcome more directly than PC–05.

Further, we believe that removing PC–05 would produce a more harmonized and streamlined measure set (83 FR 41539 through 41540). Removing this measure from the Hospital IQR Program under removal Factor 5 supports the Meaningful Measures Framework because it helps the Hospital IQR Program reach a parsimonious set of the most meaningful measures available to track patient outcomes and impact (83 FR 41567). One of the Hospital IQR Program's primary benefits to patients and the public is its ability to collect and publicly report data for patients to use in making decisions about their care. At the same time, maintaining an unnecessarily large or complicated measure set including measures that may not be as meaningful to patients hampers the Hospital IQR Program's effectiveness at presenting valuable data in a useful manner (83 FR 41544). Replacing this measure with one that is more strongly associated with broader maternal health goals aligns with the Meaningful Measures Framework and allows us to continue to effectively promote quality care.

We note that, in alignment with our focus on encouraging quality of care in maternal health, we proposed to include the Maternal Morbidity Structural Measure as early as is practicable. Due to operational procedures required to remove PC–05, however, there would be overlap with the proposed Maternal Morbidity Structural Measure in the program until PC–05 would be removed. The proposed Maternal Morbidity Structural Measure would have a reporting period beginning on October 1, 2021 through December 31, 2021, affecting the FY 2023 payment determination, which would overlap with PC–05 until its proposed removal for the CY 2024 reporting period/FY 2026 payment determination. We note that removal of PC–05 measure is contingent on the adoption of the Maternal Morbidity Structural Measure.

We invite public comment on our proposal to remove the Exclusive Breast Milk Feeding (PC–05) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

c. Proposal To Remove Three Measures Under—Removal Factor 8, Costs Associated With a Measure Outweigh the Benefit of its Continued Use in the Program

We are proposing to remove three measures under removal Factor 8, ''Costs Associated with a Measure Outweigh the Benefit of its Continued Use in the Program.'' These three measures are Admit Decision Time to ED Departure Time for Admitted Patients (ED–2); Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03); and Discharged on Statin Medication (STK–06).

(1) Admit Decision Time to ED Departure Time for Admitted Patients (ED–2)

In the FY 2016 IPPS/LTCH PPS final rule, we adopted the Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) eCQM as an option from which hospitals could choose to report to meet the self-selected eCQM data reporting requirements for the FY 2018 payment determination. We refer readers to the FY 2016 IPPS/LTCH PPS final rule for more detail on this measure (80 FR 49693 through 49698). The ED–2 eCQM evaluates the median time in minutes from admit decision time to time of departure from the emergency department (ED) for ED patients admitted to inpatient status.

A recently published systematic review by Boudi, et al. of 12 individual studies examined the association between ED boarding time (the time between the admission decision and departure from the ED) and in hospital mortality (IHM). Although the authors noted a tendency toward an association, they did not find strong evidence for an association between ED boarding and IHM.[1222] Six of the studies reviewed showed an association between ED boarding time and IHM, five showed no association, and the remaining study demonstrated an association for patients admitted to non-ICU wards and no association for patients admitted to ICU status.[1223]

The authors indicated there is variability in what is considered a cut-off time to define extended ED boarding time or prolonged ED LOS and stated that, in the U.S., prolonged ED visits have been defined as over 6 hours.[1224]

[1222] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

[1223] Boudi Z, Lauque D, Alsabri M, Ostlundh L, Oneyji C, Khalemsky A, et al. (2020) Association between boarding in the emergency department and in-hospital mortality: A systematic review. PLoS ONE 15(4): e0231253. *https://doi.org/10.1371/journal.pone.0231253.*

[1224] The authors note there is a lack of a unique cut-off time to define EDB and state that, ''[f]urther well-controlled, international multicenter studies are needed to demonstrate . . . whether there is a

In several of the studies in this systematic review demonstrating an association between ED boarding and IHM, the researchers compared mortality between patients with a boarding time period of less than 6 hours and those with a boarding time period equal or greater than 6 hours (360 minutes). We compared these timeframes to hospital performance data for the chart-abstracted version of ED–2,[1225] using the most recent data in the *Care Compare* downloadable data base for timely and effective care from January 1, 2019 through December 31, 2019. Those results show that the national average for the ED–2 median reported boarding times is 101 minutes; the ED–2 90th percentile is 31 minutes; and only 37 out of 4,028 (0.92 percent) hospitals that reported on ED–2 had an ED–2 median time equal to or greater than 360 minutes. Thus, the *Care Compare* data indicate that most hospitals do not report median boarding times that correspond with this 6-hour cutoff.

Boudi's systematic review is consistent with previous research finding conflicting results related to the association between ED crowding and inpatient mortality. For example, a study by Derose, et al. found no association between measures indicating ED crowding and inpatient mortality after controlling for patient characteristics.[1226]

In light of the inconsistency in research findings, we have reassessed the value of retaining the ED–2 eCQM in the Hospital IQR Program and are proposing to remove this measure, beginning with the CY 2024 reporting period/FY 2026 payment determination, under Factor 8, ''The costs associated with a measure outweigh the benefit of its continued use in the program.'' Pursuant to removal Factor 8, we strive to ensure that the Hospital IQR Program measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program (83 FR 41540). We believe that costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. For healthcare providers, the costs include maintaining the general administrative knowledge needed to report this measure as well as the costs associated with implementing and maintaining measure specifications in hospitals' EHR systems for all the eCQMs available for use in the Hospital IQR Program (83 FR 41568). We also recognize that CMS expends resources when maintaining information collection systems and analyzing reported data. Removing these measures would reduce provider and program costs alike. Given that recent studies indicate an inconclusive association between ED boarding times and adverse outcomes such as in-hospital mortality, the cost of the current expenditure outweighs the benefit of continued used of ED–2. Additionally, due to the operational limitations of introducing and removing eCQMs associated with the lifecycle of such measures, we propose to remove this measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

We invite public comments on our proposal to remove Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

(2) Stroke Related Electronic Clinical Quality Measures (eCQMs)

We are proposing to remove two stroke-related eCQMs:

- Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) (adopted in the set of eCQMs from which hospitals self-select for Hospital IQR Program reporting in the FY 2016 IPPS/LTCH PPS final rule, 80 FR 49693 through 49698); and
- Discharged on Statin Medication (STK–06) (adopted in the set of eCQMs from which hospitals self-select for Hospital IQR Program reporting in the FY 2016 IPPS/LTCH PPS final rule, 80 FR 49693 through 49698).

We are proposing to remove STK–03 and STK–06 under removal Factor 8, ''the costs associated with a measure outweigh the benefit of its continued use in the program.'' Under removal Factor 8, we strive to ensure that the Hospital IQR Program measure set aligns with the Meaningful Measures Framework goal of promoting improved health outcomes for beneficiaries while minimizing the overall costs associated with the program (83 FR 41540). We assessed the relative costs and benefits for both measures as described in detail in this rule.

As we assessed the relative benefits of these measures, we recognized that our measure set contains a high proportion of stroke related eCQMs. As previously finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58931), we have a total of nine eCQMs, four of which are stroke related. In order to achieve a more parsimonious measure set, we believe it is appropriate to reduce the portfolio of stroke-related eCQMs. We continue to believe that ensuring appropriate pharmacotherapy for stroke patients is an important topic and we will continue to work with relevant stakeholders to identify measures of quality and advance improved health outcomes for stroke patients. Within the eCQM portfolio of stroke measures, we identified STK–03 and STK–06 as candidates for removal based on specific considerations described in this rule.

For STK–03 specifically, the patient population (patients prescribed anticoagulation therapy, which is a type of antithrombotic therapy), can be considered a subpopulation of the global population of ischemic stroke patients captured under the STK–02 eCQM, which measures the number of patients prescribed antithrombotic therapy at hospital discharge.[1227] Further, the results of our internal review of the CY 2019 eCQM reporting indicate that fewer hospitals chose to report STK–03 than any of the other remaining three stroke-related eCQMs. In contrast, STK–02 was the most reported of the four stroke-related eCQMs for the CY 2019 eCQM reporting period. Though the STK–02 eCQM does not provide the same level of granularity as the STK–03 eCQM, we believe that the low reporting rate of STK–03 coupled with the overlap in patient populations means that the benefits of maintaining both measures in the Hospital IQR Program measure set has been reduced. Given these reduced benefits, we now believe that the costs associated with this measure outweigh the benefits of retaining this measure in the Hospital IQR Program measure set.

For STK–06 specifically, which assesses percentage of patients discharged on statin medication, we found that the updated 2019 American Heart Associations (AHA)/American Stroke Association (ASA) stroke guidelines on antiplatelet treatment indicate that STK–06 is not the most suitable measure for improving patient outcomes in stroke treatment during the

specific EDB time cut-off that results in increased IHM.''

[1225] The chart-abstracted version of ED–2 was finalized for removal in the FY 2019 IPPS/LTCH PPS final rule for the FY 2022 payment determination (83 FR 41567).

[1226] Derose S, Gabayan G, Chiu V, Yiu S, Sun B. (2014) Emergency Department Crowding Predicts Admission Length-of-Stay But Not Mortality in a Large Health System. Med Care. 2014 July; 52(7): 602–611. doi:10.1097/MLR.0000000000000141. This study of the impact of ED system crowding measures on outcomes concluded that, after controlling for patient characteristics, there was no association between measures of ED crowding and inpatient mortality.

[1227] D. Becker. 2013 Antithrombotic Drugs: Pharmacology and Implications for Dental Practice. Anesth Prog. 2013 Summer; 60(2): 72–80. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3683884/*.

acute period.[1228] [1229] We believe the body of evidence supporting the benefits of retaining STK–06 has been weakened by the findings of the AHA/ASA stroke guidelines. This is because the strongest recommendations and quality of evidence are for administration of aspirin in patients with Acute Ischemic Stroke within 24 to 48 hours after onset. Furthermore, there is only moderate quality evidence to continue STK–06, the measure of ischemic stroke patients who are prescribed or continue to take statin medication at hospital discharge.[1230] [1231] Lastly, other measures like STK–02, Discharged on Antithrombotic Therapy, and STK–05, Antithrombotic Therapy by The End of Hospital Day 2, already support our efforts to improve care and patient outcomes in the acute period. Taken together we believe that the benefit of retaining STK–06 has been reduced. Given these reduced benefits, we now believe that the costs associated with this measure outweigh the benefits of retaining this measure in the Hospital IQR Program measure set.

We believe that costs are multifaceted and include the burden associated with reporting as well as costs related to program implementation and maintenance, which are applicable both to providers and CMS (83 FR 41540). Removing STK–03 and STK–06 under Factor 8 would eliminate costs associated with implementing and maintaining these measures for the Hospital IQR Program. For healthcare providers, the costs associated with STK–03 and STK–06 include maintaining the general administrative knowledge needed to report these measures as well as the costs associated with implementing and maintaining measure specifications in hospitals' EHR systems for all the eCQMs available for use in the Hospital IQR Program (83 FR 41568). We also recognize that CMS expends resources when maintaining information collection systems and analyzing reported data. Removing these measures would reduce provider and program costs alike.

In summary, removing STK–03 and STK–06 would reduce the costs associated with them in the Hospital IQR Program while still maintaining an efficient measure set that continues to effectively promote quality care. Removing STK–03 and STK–06 supports using a parsimonious set of the most meaningful measures available to track patient outcomes and impact, in keeping with the Meaningful Measures Framework (83 FR 41567). Maintaining an unnecessarily large or complicated measure set including measures that are not meaningful to consumers and caregivers hampers the Hospital IQR Program's effectiveness (83 FR 41544). Additionally, due to the operational feasibility of introducing and removing eCQMs, we propose to remove both measures beginning with the CY 2024 reporting period/FY 2026 payment determination.

We invite public comment on our proposal to remove both the Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) and the Discharged on Statin Medication (STK–06) measures beginning with the CY 2024 reporting period/FY 2026 payment determination.

8. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

a. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2023 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2023 Payment Determination:

Measures for the FY 2023 Payment Determination		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579

[1228] Kennedy J, Hill MD, Ryckborst KJ, Eliasziw M, Demchuk AM, Buchan AM; FASTER Investigators. Fast Assessment of Stroke and Transient Ischaemic Attack to Prevent Early Recurrence (FASTER): A randomised controlled pilot trial. Lancet Neurol. 2007; 6:961–969. doi:10.1016/S1474–4422(07)70250–8.

[1229] Yoshimura S, Uchida K, Daimon T, Takashima R, Kimura K, Morimoto T; on behalf of the ASSORT Trial Investigator. Randomized controlled trial of early versus delayed statin therapy in patients with acute ischemic stroke: ASSORT Trial (Administration of Statin on Acute Ischemic Stroke Patient). Stroke. 2017;48:3057–3063. doi:10.1161/STROKEAHA.117.017623.

[1230] Powers WJ, Rabinstein AA, Ackerson T, Adeoye OM, Bambakidis NC, Becker K, Biller J, Brown M, Demaerschalk BM, Hoh B, Jauch EC, Kidwell CS, Leslie-Mazwi TM, Ovbiagele B, Scott PA, Sheth KN, Southerland AM, Summers DV, Tirschwell DL; on behalf of the American Heart Association Stroke Council. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2019; 50:e344–e418 doi: 10.1161/STR.0000000000000211.

[1231] Sandercock PA, Counsell C, Tseng MC, Cecconi E. Oral antiplatelet therapy for acute ischaemic stroke. Cochrane Database Syst Rev. 2014:CD000029. doi: 10.1002/14651858.CD000029.pub3.

Measures for the FY 2023 Payment Determination		
Short Name	**Measure Name**	**NQF #**
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity***	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.c. of the preamble of this proposed rule for more detail.

** In the FY 2020 IPPS/LTCH PPS final rule, we finalized our proposal to remove the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and to replace it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** The Maternal Morbidity Structural Measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.a. of the preamble of this proposed rule for more detail.

**** Finalized in the FY 2020 IPPS/LTCH PPS final rule to add Safe Use of Opioids – Concurrent Prescribing to the eCQM measure set, beginning with the CY 2021 reporting period/FY 2023 payment determination with a clarification and update (84 FR 42449 through 42459).

b. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2024 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2024 Payment Determination and Subsequent Years:

Measures for the FY 2024 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436

Measures for the FY 2024 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity***	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.c. of the preamble of this proposed rule for more detail.

** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** The Maternal Morbidity Structural Measure is being proposed for adoption in this year's proposed rule. We refer readers to section IX.C.5.a. of the preamble of this proposed rule for more detail.

**** Reporting on the Safe Use of Opioids – Concurrent Prescribing eCQM is mandatory for the FY 2024 payment determination and subsequent years.

c. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2025 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2025 payment determination:

Measures for the FY 2025 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Claims and Electronic Data Measures		

Measures for the FY 2025 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
Hybrid HWM***	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity****	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids*****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01******	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02******	Hospital Harm—Severe Hyperglycemia Measure	3533e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.c. of the preamble of this proposed rule for more detail.

** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** In this proposed rule, we are proposing to adopt the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023-June 30, 2024 reporting period, impacting the FY 2026 payment determination.

**** The Maternal Morbidity Structural Measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.a. of the preamble of this proposed rule for more detail.

***** Reporting on the Safe Use of Opioids measure is mandatory for the FY 2024 payment determination and subsequent years.

****** The Hospital Harm-Severe Hypoglycemia Measure and the Hospital Harm-Severe Hyperglycemia Measure are being proposed for adoption in this proposed rule. We refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. of the preamble of this proposed rule for more detail.

d. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2026 Payment Determination

This table summarizes the previously finalized and newly proposed Hospital IQR Program measure set for the FY 2026 payment determination:

Measures for the FY 2026 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage Among Health Care Personnel	N/A
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579

Measures for the FY 2026 Payment Determination and Subsequent Years		
Short Name	**Measure Name**	**NQF #**
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Claims and Electronic Data Measures		
Hybrid HWM**	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Hybrid HWR***	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity****	Maternal Morbidity Structural Measure	N/A
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
Safe Use of Opioids *****	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01 ******	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02 ******	Hospital Harm—Severe Hyperglycemia Measure	3533e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* The COVID-19 Vaccination Coverage Among Health Care Personnel measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.c. of the preamble of this proposed rule for more detail.

** In this proposed rule, we are proposing to adopt the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with one voluntary reporting period (July 1, 2023-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023- June 30, 2024 reporting period, impacting the FY 2026 payment determination.

*** In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

**** The Maternal Morbidity Structural Measure is being proposed for adoption in this proposed rule. We refer readers to section IX.C.5.a. of the preamble of this proposed rule for more detail.

***** Reporting on the Safe Use of Opioids measure is mandatory for the FY 2024 payment determination and subsequent years.

****** The Hospital Harm-Severe Hypoglycemia Measure and the Hospital Harm-Severe Hyperglycemia Measure are being proposed for adoption in this proposed rule. We refer readers to sections IX.C.5.d.1. and IX.C.5.d.2. of the preamble of this proposed rule for more detail.

9. Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality and cost improvements through the inpatient hospital setting. Additionally, the emergence of COVID–19 has highlighted various impacts on measure outcomes and care of patients, which we believe are important to address. We have identified potential future measure or topics for future development, which we believe address areas that are important to stakeholders, but which are not currently covered in the Hospital IQR Program measure set. Therefore, we are seeking stakeholder feedback on potential new measures and future considerations for the Hospital IQR Program. These are discussed in more detail later in this section.

a. Potential Future Development and Inclusion of a 30-Day, All-Cause Mortality Measure for Patients Admitted With COVID–19 Infection

We are working to learn more about the impact of the COVID–19 infection on measure outcomes, particularly readmission and mortality measures, and about how the burden of the PHE for COVID–19 influences hospitals' ability to care for patients. To support our efforts, we are considering the potential future inclusion of a new hospital-level measure of all-cause mortality for Medicare beneficiaries admitted with COVID–19 infection (COVID–19 mortality measure). Such a measure would likely be similar to other hospital-level mortality measures currently in use in CMS programs, such as the AMI and Heart Failure 30-day mortality measures adopted for the Hospital IQR Program in the CY 2007 OPPS/ASC final rule (71 FR 68201) and the Pneumonia 30-day mortality measure adopted for the Hospital IQR Program in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47346 through 47351). These measures were later adopted for HVBP in the FY 2011 Hospital VBP final rule (76 FR 26497 through 26511). For example, the measure would likely be constructed with the measure cohort including patients admitted with COVID–19 based on principal or in select cases based on secondary diagnoses, the outcome being mortality within a specified number of days from admission (such as 30 days), and risk adjustment based on clinical factors and constructed using hierarchical modelling. The measure would use administrative claims data; however, development and reporting data would not include the January 1, 2020 through June 30, 2020 data excluded in the blanket ECE issued in response to the PHE for COVID–19.

Public reporting of this measure would not be feasible until at least FY 2023 due to the time required for measure development, testing, and production, as well as statutorily required pre-rulemaking (inclusion on the Measures Under Consideration list for public comment and review by the MAP) and notice and comment rulemaking. To inform our measure development, we are currently seeking public comment on the potential future inclusion of a COVID–19 mortality measure in the Hospital IQR Program. Specifically, we are seeking input on:

- The timeline and approach for implementing a COVID–19 mortality measure. We seek stakeholder comment on balancing the priority of obtaining rapid information to improve quality of care for patients during the COVID–19 pandemic with the potential benefits of a phased approach to implementation, that might include, for example, a dry run, voluntary reporting, and/or confidential reporting prior to public reporting on the *Care Compare* website;
- The population (type of patients) to include in the COVID–19 mortality measure cohort. Specifically, diagnosis codes for principal diagnosis of COVID–19, and other key diagnoses, such as pneumonia or sepsis, if COVID–19 is coded as a secondary diagnosis present on admission;
- The potential inclusion of both Medicare FFS beneficiaries and Medicare Advantage patients, as feasible;
- Risk factors we should consider adjusting for in the measure, such as clinical risk factors or comorbidities available in administrative claims data; and
- The potential stratification of measure results, as feasible, such as by social risk factors, geographic location, and/or prevalence or burden of COVID–19 disease, and how to define these characteristics.

b. Potential Future Inclusion of a Hospital-Level, Risk Standardized Patient Reported Outcomes Measure Following Elective Primary Total Hip and/or Total Knee Arthroplasty

(1) Background

Approximately 6 million adults aged 65 or older suffer from osteoarthritis in the US.[1232] Osteoarthritis accounts for more than half of all arthritis-related hospitalizations,[1233] and in 2013 there were approximately 1,023,000 hospitalizations for osteoarthritis.[1234] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[1235] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[1236] Elective total hip arthroplasty (THA) and total knee arthroplasty (TKA) are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[1237] THA and TKA offer significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[1238] [1239] [1240] [1241] However, not all patients experience benefit from these procedures.[1242] Many patients note that their preoperative expectations for functional improvement have not been met.[1243] [1244] [1245] [1246] In addition, clinical

[1232] Arthritis Foundation. Arthritis By the Numbers Book of Trusted Facts and Figures. 2018: *https://www.arthritis.org/Documents/Sections/About-Arthritis/arthritis-facts-stats-figures.pdf.* Accessed March 8, 2019.

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practice variation has been well documented in the U.S.,[1247] [1248] [1249] readmission and complication rates vary across hospitals,[1250] [1251] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[1252] For example, data from the United Kingdom demonstrates that there is a greater than 15 percent difference across hospitals in the proportion of patients showing improvement after surgery.[1253] [1254]

Peri-operative care and care coordination across provider groups and specialties have important effects on clinical outcomes.[1255] [1256] The goal of a hospital-level outcome measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. THA and TKA procedures provide a suitable environment for optimizing care, as there are many studies indicating how hospitals and providers can improve outcomes of their patients by addressing aspects of pre-, peri-, and postoperative care.[1257] [1258] [1259] [1260] [1261] [1262]

Due to the absence of large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, in November 2015 CMS established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development. Requirements for successful submission of PRO data for eligible elective primary THA/TKA procedures were identified by CMS in the 2015 CJR final rule (80 FR 73274). This Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty performance measure (THA/TKA) (THA/TKA PRO–PM) was developed and tested using PRO and risk variable data collected from and submitted by CJR participant hospitals. PRO data from the first few performance years for the CJR model revealed hospital-level variation in these outcomes across U.S. hospitals, although the full degree and extent of variation is unknown.

In October 2017, we launched the Meaningful Measures Framework to identify high priority areas for quality measurement that improve patient outcomes while also reducing burden on providers.[1263] The initiative captures the agency's vision in evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The scope of the Meaningful Measures Framework continues to evolve as the health care environment continues to change. Meaningful Measures 2.0 is currently underway and aims to promote better collection and integration of patients' voices by incorporating PRO measures that are embedded into the clinical workflow, are easy to use, and reduce reporting burden.[1264] The THA/TKA PRO–PM is fully developed aligns with these Meaningful Measures 2.0 goals.

Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[1265] [1266] [1267] [1268] [1269] [1270] [1271] [1272] [1273] [1274] [1275] [1276] [1277] are influenced by

Often are Patient and Surgeon Recovery Expectations for Total Joint Arthroplasty Aligned? Results of a Pilot Study. *HSS journal: The musculoskeletal journal of Hospital for Special Surgery.* 2011;7(3):229–234.

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[1263] CMS' Meaningful Measures Framework can be found at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1264] *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

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Continued

a range of improvements in care,[1278] [1279] [1280] [1281] [1282] [1283] [1284] [1285] and demonstrate hospital-level variation even after patient case mix adjustment.[1286] [1287] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.[1288]

(2) Overview of Measure

The THA/TKA PRO–PM reports the hospital-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older.

Substantial clinical improvement would be measured by achieving a pre-defined improvement in score on joint-specific PRO instruments, measuring hip or knee pain and functioning, from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 300 to 425 days following surgery). For additional details regarding the measure specifications, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report, available on the CMS website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*).

Several stakeholder groups were engaged throughout the development process of the THA/TKA PRO–PM, as required in the Measures Management System (MMS) Blueprint,[1289] including a Technical Advisory Group (TAG), a Patient Working Group, and a national, multi-stakeholder Technical Expert Panel (TEP) consisting of a diverse set of stakeholders, including providers and patients. These groups were convened by the measure developer under contract with CMS and who provided feedback on the measure concept, outcome, cohort, risk model variables, reporting results, and data collection. We also received multiple public comments used to support the development of this measure in the 2015 CJR final rule (80 FR 73274).

The THA/TKA PRO–PM (MUC20–0003) was included in the publicly available ''2020 Measures Under Consideration List.'' [1290] The MAP supported the measure, as referenced in the 2020–2021 Final Recommendations report to HHS and CMS.[1291] This measure was submitted for NQF review in March 2020.[1292] In November 2020, the NQF endorsed the THA/TKA PRO–PM (NQF#3559).

(3) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. The measure uses PRO and limited patient-level risk factor data (described in section IX.C.9.b. of the preamble of this proposed rule) collected by hospitals preoperatively and postoperatively. The measure includes two joint-specific PRO instruments—the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients and the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. Additionally, hospitals submit either the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global or the Veterans RAND 12-Item Health Survey (VR–12), from which Mental Health subscale preoperative scores and used for risk adjustment. Claims data are used to identify eligible elective primary THA/TKA procedures for the measure cohort and additional variables for risk adjustment and accounting for response bias, including patient demographics and clinical comorbidities up to 12 months prior to surgery. The Medicare's Enrollment Database (EDB) identifies Medicare FFS enrollment and race, and the Master Beneficiary Summary File allows for determination of dual eligibility status. Demographic information from the U.S. Census Bureau's American Community Survey [1293] allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index score.

(4) Outcome

In response to extensive feedback from orthopedic experts to capture PRO data for the many patients whose ''12-month'' postoperative appointments

arthroplasty: A systematic review. Br Med Bull. 2012;101:81–103.

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[1289] CMS Measures Management System Blueprint (Blueprint v 16.0). CMS. 2020. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[1290] 2020 Measures Under Consideration List. Available at *https://www.cms.gov/media/492911.*

[1291] MAP 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. NQF. 2021. Available at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

[1292] NQF Quality Positioning System. Available at *https://www.qualityforum.org/QPS.*

[1293] American Community Survey, available at: *https://www.census.gov/programs-surveys/acs.*

actually occur in months 10 to 14 (300 to 425 days) following surgery, the THA/TKA PRO–PM was modified slightly to reflect a longer postoperative assessment period. Specifically, the postoperative assessment period was extended from 270 to 365 days in initial development to 300 to 425 days.

The measure outcome (numerator) is the risk-standardized proportion of patients undergoing elective primary THA/TKA who meet or exceed a substantial clinical improvement threshold between preoperative and postoperative assessments on two joint-specific PRO instruments. The measure outcome will assess patient improvement in PROs using the HOOS, JR following elective primary THA and the KOOS, JR following elective primary TKA. PRO data will be collected 90 to zero days prior to surgery and 300 to 425 days following surgery. These PRO collection periods align with typical patient visits prior to and following surgery.

The measure outcome defines patient improvement as a binary outcome (''Yes''/''No'') of meeting or exceeding the pre-defined improvement threshold between preoperative and postoperative assessments on the joint-specific PRO instruments: Specifically, for THA patients, meeting or exceeding the threshold of 22 points on the HOOS, JR and, for TKA patients, meeting or exceeding the threshold of 20 points on the KOOS, JR.

(5) Cohort

The measure cohort (denominator) is Medicare FFS beneficiaries aged 65 years and older undergoing elective primary THA/TKA procedures as inpatients in acute care hospitals. We are aware that elective primary THA/TKA procedures are increasingly occurring in hospital outpatient and ambulatory surgical center settings and we are evaluating options to address measurement of those procedures and settings.

(6) Inclusion and Exclusion Criteria

The THA/TKA PRO–PM includes patients who are—

- Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission and enrolled in Part A during the index admission;
- Aged 65 or older; and
- Discharged alive from non-Federal short-term acute care hospital.

The measure includes only elective primary THA/TKA procedures (patients with fractures and revisions are not included).

The measure excludes patients with staged procedures, defined as more than one elective primary THA or TKA performed on the same patient during distinct hospitalizations during the measurement period.

(7) Risk Adjustment

The risk model was developed with clinically relevant risk variables identified by public comment in the 2015 CJR final rule (80 FR 73274), the TEP, and expert orthopedic consultants and supported by empirical analyses, and includes risk variables collected with PRO data by hospitals in the CJR model. The preoperative score of the Mental Health subscale from two global PRO instruments (the PROMIS-Global or the VR–12) collected with CJR PRO data is included as a risk variable. In addition, the risk model includes a validated, one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, since poorly or incompletely collected PRO data may be asymmetrically distributed across lower socioeconomic or disadvantaged populations and thus potentially affect measure scores, the measure developer used empirical analyses and stakeholder input to develop an approach to account for response bias in the measure calculation. The approach uses comorbidities and social risk factors—including non-White race, dual eligibility, and AHRQ SES index lowest quartile—to predict response to the PRO survey. Weighting the responders based on their likelihood of response (given their patient characteristics) helps reduce non-response bias when calculating the RSIR.

For additional details regarding the approach to risk adjustment and the full risk model, we refer readers to the Patient-Reported Outcomes (PROs) Following Elective Primary Total Hip and/or Total Knee Arthroplasty: Hospital-Level Performance Measure—Measure Methodology Report), available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*).

(8) Measure Calculation

The hospital-level THA/TKA PRO–PM measure result is calculated by aggregating all patient-level results across the hospital. At the hospital level, this measure would be calculated and presented as a RSIR, producing a performance measure per hospital which accounts for patient case mix, addresses potential non-response bias, and represents a measure of quality of care following primary elective THA and TKA. Response rates for PRO data for this measure would be calculated as the percentage of elective primary THA or TKA procedures for which complete and matched preoperative and postoperative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each hospital and may be reported with measure results for transparency.

As described in section IX.C.9.b.(7). of the preamble of this proposed rule, the measure developer under contract with CMS convened several stakeholder groups, including providers and patients, throughout measure development. Providers noted that there was a need for sufficient time and resources for initial set up and resources needed to collect data either internally or externally. As a result, we are considering a phased implementation approach for this measure. For example, similar to other novel measures recently adopted, such as the Hybrid HWR measure finalized for inclusion in the Hospital IQR Program in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465), we are considering first allowing hospitals to submit their data voluntarily before it would become mandatory for reporting as part of the Hospital IQR Program.

We are considering three different implementation approaches. One approach would be that hospitals collect their own data and send to CMS for measure calculation. Another approach would be that collection would occur by an external entity, such as through a vendor or CMS. Lastly, hospitals could collect their own data and send their data to a registry or other entity for storage, standardization, and submission to CMS for measure calculation.

We received feedback from patients and providers that they would like to utilize their PRO results as part of the shared decision-making process and had a desire for flexible data collection modes (telephone, paper, electronic). Patients were more willing to report data if they knew the survey was from their provider, they understood the importance and use of the survey, and they had access to their own survey responses.

Providers expressed concerns over survey fatigue, resources needed to collect data, and integration with EHRs. We understand the importance of aligning data collection and data submission efforts for hospital reporting of PRO data and providing a way for hospitals to integrate the collection into

EHRs so the PRO data are available at the point of care.

We invite public comment on the possible future inclusion of the THA/TKA PRO–PM in the Hospital IQR Program.

We also invite public comment on other aspects of the measure related to future implementation. Specifically, we are seeking public comment on the following:

- A phased approach to implementation, including voluntary followed by mandatory reporting, and the timing/duration of such reporting periods.
- The mechanism of data collection and submission, including anticipated barriers and solutions to data collection and submission.
- The required thresholds for the quantity of data (that is, number of completed PRO instruments) hospitals should submit for voluntary and mandatory reporting.
- The application of the THA/TKA PRO–PM measure to settings such as hospital outpatient departments, ambulatory surgical centers, or hospital inpatient procedures followed by observation stays, such as through aligned PRO–PMs across the relevant measurement programs; CMS recognizes that over time, more THA and TKA procedures may be performed outside of the inpatient setting; as finalized in the CY 2021 OPPS/ASC final rule, THA and TKA procedures have been removed from CMS' inpatient only (IPO) procedure list (82 FR 59385, 84 FR 61355) and added to the ASC covered procedures list (CPL) (84 FR 61388, 85 FR 86146).

c. Potential Future Efforts To Address Health Equity in the Hospital IQR Program

Significant and persistent inequities in health care outcomes exist in the United States.[1294] Inequities in the social determinants of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks. Therefore, we are committed to achieving equity in health care outcomes, including by improving data collection to better measure and analyze disparities across programs and policies.[1295] Please see Closing the Health Equity Gap in CMS Quality Programs—A Request for Information, in section IX.B. of the preamble of this proposed rule, for additional information about our current disparity methods and its potential expansion.

We have also identified potential opportunities specific to the Hospital IQR Program where we could leverage current measures or develop new measures to address the gap in existing health inequities. These opportunities include the stratification of HWR measure data by both dual eligibility and race/ethnicity, and the inclusion of a structural measure assessing the degree of hospital leadership engagement in health equity performance data.

(1) Potential Future Confidential Stratified Reporting for the Hospital-Wide All-Cause Unplanned Readmission Measure Using Both Dual Eligibility and Race/Ethnicity

(a) Background

As described in section IX.B. of the preamble of this proposed rule, where we discuss Closing the Health Equity Gap in CMS Hospital Quality Programs—A Request for Information, we currently provide hospitals with confidential, hospital-specific reports (HSRs) containing performance results of six condition-specific readmission measures stratified by dual-eligibility status (82 FR 41589, 84 FR 42497 through 42500).

(b) Potential Future Expansion of Hospital-Wide All-Cause Unplanned Readmission (HWR) Measure Data and Stratification

We are seeking comment on potentially expanding our efforts to provide results of the Within- and Across-Hospital Disparity Methods to promote health equity and improve healthcare quality. Specifically, we are seeking comment on the idea of stratifying the performance results of the Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF# 1789) by dual eligibility and indirectly estimated race and ethnicity, as described in section IX.B. of the preamble of this proposed rule. We also seek comment on the idea of stratifying said performance results by disability status and seek suggestions for appropriate measures of disability status that could be derived from administrative data or self-reporting for this purpose. Results would be presented if technically feasible, adequately representative, and statistically reliable.

We believe that concurrently reporting equity results for the HWR claims-only measure in addition to the six condition-specific measures already stratified by dual eligibility would be advantageous as the measures often provide complimentary insights about different dimensions of hospital quality.[1296] In addition, the HWR claims-only measure includes a larger patient population, allowing hospitals that may be too small to have meaningful results for condition-specific measures to receive stratified results for the HWR claims-only measure. Stratification of the HWR claims-only measure, by both dual eligibility, indirectly estimated race and ethnicity and potentially by disability status would provide additional information regarding disparities measured within individual hospitals and across hospitals nationally.

We are considering an incremental approach to public reporting, first providing the HWR claims-only measure stratification results (by both dual eligibility and race/ethnicity) in confidential HSRs. This approach would allow stakeholders an opportunity to become more familiar with, and gain comfort with, interpreting stratified results for the HWR claims-only measure using both dual eligibility and indirect estimation of race and ethnicity, prior to anticipated future public reporting of stratified measure data. Any proposal to display stratified quality measure data for any measures on the *Care Compare* website, or expand stratified reporting to additional social risk factors, would be made through future rulemaking. We anticipate being able to provide the data in the HSRs in spring 2022. We intend to consider feedback on potential disability status stratification for future updates of these measures.

We invite public comment on the following:

- The possibility of confidentially reporting in HSRs stratified results using indirectly estimated race and ethnicity, dual eligibility status and potentially by disability status, for the Hospital-wide Readmission claims-only measure, using both methods (within and across hospitals).
- The possibility of publicly reporting stratified results using indirectly

[1294] United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at: *https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*.

[1295] Centers for Medicare Services. *CMS Quality Strategy*. (2016). *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf*.

[1296] Rosen AK, Chen Q, Shwartz M, Pilver C, Mull HJ, Itani KF, Borzecki A. Does Use of a Hospital-wide Readmission Measure Versus Condition-specific Readmission Measures Make a Difference for Hospital Profiling and Payment Penalties? Med Care. 2016 Feb;54(2):155–61. doi: 10.1097/MLR.0000000000000455. PMID: 26595224.

estimated race and ethnicity, dual eligibility and potentially by disability status, publicly on *Care Compare,* after at least one year of confidential reporting for the Hospital-Wide Readmission claims-only measure.

(2) Potential Future Reporting of a Structural Measure To Assess the Degree of Hospital Leadership Engagement in Health Equity Performance Data

To ensure that all Medicare patients receive excellent care, regardless of individual characteristics, such as dual eligibility status, race, ethnicity, and disability status, we believe that organizational leadership and culture can play an essential role in advancing equity goals. The Agency for Healthcare Research and Quality (AHRQ)[1297] and The Joint Commission (TJC)[1298] have both published information on the important role of health care organizational leadership in setting an organizational culture of quality and safety. We are committed to supporting health care organizations in building a culture of equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. Hospital leadership can be instrumental in setting specific, measurable, attainable, relevant, and time-based goals, to assess progress towards achieving equity priorities and ensuring care is equally accessible to all individuals.

To improve public transparency, we are seeking comment on the potential future collection of one or more attestation-based structural measure(s), to be developed, assessing priority domains related to organizational commitment to health equity including:

- The degree to which the hospital organization regularly examines existing algorithms for the presence of bias, and regularly shares these findings with the hospital organization's leadership and board of directors;
- The presence of the hospital organizational *disparities impact statement,* along the lines of what is discussed in the CMS publication ''Building an Organizational Response to Health Disparities: Disparities Impact Statement'' [1299] which identifies and prioritizes actionable steps towards addressing health disparities;
- The presence of an updated *language access plan*[1300], as defined by the CMS Office of Minority Health, to competently care for individuals with limited English proficiency;
- The presence of an updated *communication access plan*[1301], as described by the CMS Office of Minority Health, to competently care for individuals who have visual or sensory disabilities;
- The degree to which the hospital's electronic health record system has capabilities to collect demographic data elements (such as race, ethnicity, sex, sexual orientation and gender identity (SOGI), primary language, and disability status) in alignment with national data collection[1302] and interoperable exchange standards; [1303] [1304] and
- The degree to which the hospital conducts staff training on best practices in collection of demographic information.

We believe these types of organizational commitment structural measure(s) would build on the current health disparities reporting, and support hospitals in quality improvement, efficient, effective use of resources, and leveraging available data. As defined by AHRQ, structural measures aim to ''give consumers a sense of a health care provider's capacity, systems, and processes to provide high-quality care.'' [1305] We acknowledge that collection of this structural measure may impose administrative and/or reporting requirements for hospitals. To allow stakeholders an opportunity to become more familiar with, and gain comfort with, components of the structural measure related to organizational commitment to health equity performance, we envision an incremental approach to required reporting, starting first with a voluntary reporting period. Any future technical specifications or plans to display results of the structural measure on *Care Compare* or successor website would be made through future rulemaking. We are interested in obtaining feedback from stakeholders on conceptual and measurement priorities for better illuminating organizational commitment to health equity, including review of hospital outcomes stratified by social risk factors. We also seek feedback on an appropriate measure regarding organizational commitment to health equity and accessibility for individuals with intellectual and developmental disabilities.

8. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. In order to successfully participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements.

Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the previous description. In accordance with the statute, the FY 2022 payment determination will begin the eighth year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular

[1297] Agency for Healthcare Research and Quality. Leadership Role in Improving Safety. 2019. *https://psnet.ahrq.gov/primer/leadership-role-improving-safety.*

[1298] The Joint Commission. Sentinel Event Alert. 2009 Aug 27;(43):1–3 *https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_43pdf.pdf?db=web&hash=595C815B483DA56EDF745A94F95326F4.*

[1299] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities. 2018. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.*

[1300] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities: Guide to Developing a Language Access Plan. 2018. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Language-Access-Plan.pdf.* A language access plan is defined as a document that spells out how to provide services to individuals who are non-English speaking or have limited English proficiency.

[1301] Centers for Medicare and Medicaid Services. Improving Communication Access for Individuals Who Are Blind or Have Low Vision. *https://www.cms.gov/files/document/omh-visual-sensory-disabilities-brochure-508c.pdf.*

[1302] 2015 Edition Cures Update certification criteria Demographic Data. 45 CFR 170.315(a)(5)

[1303] 2015 Edition Cures Update Certification Criteria Standardized API for Patient and Population Services. 45 CFR 170.315(g)(10)

[1304] 2015 Edition Cures Update Certification Criteria United States Core Data for Interoperability (USCDI). 45 CFR 213

[1305] Agency for Healthcare Research and Quality. Types of Health Care Quality Measures. 2015. *https://www.ahrq.gov/talkingquality/measures/types.html.*

period of time. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We are not proposing any changes to these policies in this proposed rule.

The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical specifications used for electronic clinical quality measures (eCQMs). The Annual Update contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2021 reporting period/FY 2023 payment determination, hospitals submitted eCQM data using the May 2020 Annual Update and any applicable addenda. Updates include code updates, logic corrections, alignment with current clinical guidelines, and additional guidance for hospitals and electronic health record (EHR) vendors. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data through the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). The QualityNet Secure Portal is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

We also refer readers to section VIII.A. of this proposed rule where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the FHIR standard (as described in that section).

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). In this proposed rule, we are proposing to: (1) Update references to the QualityNet website, and (2) use the term ''QualityNet security official'' instead of ''QualityNet Administrator''.

(1) Proposal To Update References to the QualityNet Website in the Hospital IQR Program Regulation Text

In November 2020, we launched a redesigned QualityNet website, and updated the URL from *QualityNet.org* to *QualityNet.cms.gov*.[1306] As a result, we are proposing to update the references to this CMS resource in the Hospital IQR Program regulation text. Specifically, we are proposing to remove reference to the *QualityNet.org* URL in two places:

- At 42 CFR 412.140(a)(1) by revising the sentence from ''Register on *QualityNet.org*, before it begins to report data'' to ''Register on the QualityNet website, before it begins to report data''; and
- At 42 CFR 412.140(c)(2)(i) by revising the sentence from ''Specific requirements for submission of a request for an exception are available on *QualityNet.org*'' to ''Specific requirements for submission of a request for an exception are available on the QualityNet website.''

We believe that updating the references to remove a specific URL allows for future iterations and updates to the website as technology evolves over time.

We invite public comment on our proposals to update references to the QualityNet website at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i).

(2) Proposal to Update Reference to QualityNet Administrator

The previously finalized QualityNet security administrator requirements, including setting up a QualityNet account and the associated timelines, are described at 42 CFR 412.140(a)(2), 42 CFR 412.140(e)(2)(iii), and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639 through 51640).

In this proposed rule, we propose to use the term ''QualityNet security official'' instead of ''QualityNet Administrator'' or ''QualityNet System Administrator''. This proposed update in terminology would not change the individual's responsibilities or add burden, and would align with the Hospital Outpatient Quality Reporting (OQR) Program and other programs.[1307] The term ''security official'' would refer to ''the individual(s)'' who have responsibilities for security and account management requirements for a hospital's QualityNet account.

Therefore, we propose to revise existing language at 42 CFR 412.140(a)(2) by replacing ''QualityNet Administrator'' with ''QualityNet security official.'' If finalized, the revised paragraph (a)(2) would read: ''Identify and register a QualityNet security official as part of the registration process under paragraph (a)(1) of this section.''

In addition, we propose to revise existing language at 42 CFR 412.140(e)(2)(iii) by replacing ''QualityNet system administrator'' with ''QualityNet security official.'' If finalized, the revised paragraph (e)(2)(iii) would read: ''Contact information for the hospital's chief executive officer and QualityNet security official, including each individual's name, email address, telephone number, and physical mailing address.''

We invite public comment on our proposals to update references to the QualityNet security official at 42 CFR 412.140(a)(2) and 42 CFR 412.140(e)(2)(iii).

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We are not proposing any changes to these policies in this proposed rule.

e. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018

[1306] QualityNet Migration from *QualityNet.org* to *QualityNet.cms.gov*. Available at: *https://qualitynet.cms.gov/news/5fa2f7ccfa00d50025576586.*

[1307] Medicare Program; CY 2021 Medicare hospital outpatient prospective payment system. 85 FR 86182.

IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58940).

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38368 through 38361), we finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41603 through 41604), as well as to the CY 2020 reporting period/FY 2022 payment determination and the CY 2021 reporting period/FY 2023 payment determination in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42503).

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505), we finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a progressive increase in the numbers of required reported quarters of eCQM, from one self-selected quarter of data to four quarters of data over a three-year period (85 FR 58939). For the CY 2021 reporting period/FY 2023 payment determination, hospitals are required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs. For the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to report three self-selected calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids eCQM. For the CY 2023 reporting period/FY 2025 payment determination and subsequent years, hospitals are required to report four calendar quarters of data for each required eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids eCQM. We also clarified in the FY 2021 IPPS/LTCH PPS final rule that until hospitals are required to report all four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination, they may submit either consecutive or nonconsecutive self-selected quarters of data (85 FR 58939). While we are not proposing any changes to these policies in this proposed rule, we would like to clarify in case there is any confusion that beginning with the CY 2021 reporting period/FY 2023 payment determination, the self-selected eCQMs must be the same eCQMs across quarters in a given reporting year.

(2) Proposed Updates to Certification Requirements for eCQM Reporting

In this proposed rule, we are proposing a date after which Hospital IQR Program participants must use technology certified to the 2015 Edition Cures Update and clarifying the policy that certified technology must support the reporting requirements for all available eCQMs.

(a) Proposal To Require the Use of Technology Certified to the 2015 Edition Cures Update Criteria Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

(i) Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41604 through 41607), we finalized a policy to require hospitals to use the 2015 Edition certification criteria for the CY 2019 reporting period/FY 2021 payment determination and subsequent years to align the Hospital IQR Program with the Medicare Promoting Interoperability Program. In May 2020, the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) updated the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). The 2015 Edition Cures Update revises the clinical quality measurement criterion at 45 CFR 170.315(c)(3) to refer to CMS QRDA Implementation Guides (IGs) and removes the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25686). The revision was responsive to industry feedback that the health IT certified to the prior ''CQMs-report'' criterion was only or primarily being used to submit eCQMs for CMS reporting programs (85 FR 25688). These updates were finalized to reduce burden on health IT developers under the ONC Health IT certification program (85 FR 25686) and have no impact on providers' existing reporting practices for CMS programs.

The ONC 21st Century Cures Act final rule provided health IT developers up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers (85 FR 25670). On November 4, 2020, ONC issued an interim final rule with comment entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereafter, ''ONC interim final rule'') (85 FR 70064). In the ONC interim final rule ONC extended the compliance deadline for the update to the Clinical Quality Measures-Report criterion until December 31, 2022 (85 FR 70075). During the period until December 31, 2022, health IT developers are expected to continue supporting technology certified to the prior version of the ONC certification criteria for use by their customers (85 FR 84816).

In the CY 2021 PFS final rule (85 FR 84825 through 84828), we finalized our proposal to expand flexibility under the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and for subsequent years to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized for reporting eCQMs in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608), or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961). We adopted this flexible approach to encourage hospitals to be early implementers of the 2015 Edition Cures Update while remaining in compliance with Hospital IQR Program data submission requirements and maintaining alignment with requirements in the Medicare Promoting Interoperability Program.

(ii) Proposal

In this proposed rule, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we are proposing to require hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program data. We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25665).

We invite public comment on our proposal to require hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years.

(b) Requiring EHR Technology To Be Certified to All Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We are not proposing any changes to this policy in this proposed rule. We note that if our proposal to require hospitals to use the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination is finalized, then all available eCQMs used in the Hospital IQR Program for the CY 2023 reporting period/FY 2025 payment determination and subsequent years would need to be reported using certified technology updated to the 2015 Edition Cures Update.

(3) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format, (2) may use third parties to submit QRDA I files on their behalf, and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) and the FY 2020 IPPS/LTCH PPS final rule (85 FR 58940), in which we stated that we expect QRDA I files to reflect data for one patient per file per quarter, and identified the five key elements that are utilized to identify the file:

- CMS Certification Number (CCN);
- CMS Program Name;
- EHR Patient ID;
- Reporting period specified in the Reporting Parameters Section per the CMS Implementation Guide for the applicable reporting year, which is published on the eCQI Resource Center website at: *https://ecqi.healthit.gov/QRDA;* and
- EHR Submitter ID (beginning with the CY 2021 reporting period/FY 2023 payment determination).

We are not proposing any changes to these policies in this proposed rule.

(4) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR and Medicare Promoting Interoperability Programs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline may be moved to the next business day if it falls on a weekend or Federal holiday. We are not proposing any changes to these policies in this proposed rule.

f. Data Submission and Reporting Requirements for Hybrid Measures

In this proposed rule, we are proposing that hybrid measures comply with the same certification requirements and timeline as eCQMs. This proposal is in alignment with the updates, as previously discussed, for eCQMs requiring the use of certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2023 reporting period/CY 2025 payment determination.

(1) Background

The Hospital IQR Program recently adopted hybrid measures into the program's measure set. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid Hospital-Wide Readmission (HWR) measure for the CY 2018 reporting period. In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) such that, beginning with the FY 2026 payment determination, hospitals are required to report on the Hybrid HWR measure (84 FR 42479). We also finalized several requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508). We also refer readers to section VIII.C.8.f. of the preamble of this proposed rule for more information on our proposal to adopt the Hybrid Hospital-Wide Mortality measure.

(2) Certification and File Format Requirements

(a) Background

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 19498 through 19499), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), and the CY 2021 PFS final rule (85 FR 84472) for our previously adopted policies regarding certification and file format requirements for hybrid measures in the Hospital IQR Program.

In the CY 2021 PFS final rule (85 FR 84825 through 84828), we finalized flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41537 through 41608) or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961, 85 FR 50271), beginning with the CY 2020 reporting period/FY 2022 payment determination and subsequent years. The Hospital IQR Program offers flexibility to meet hybrid measure submission requirements to facilitate successful reporting during a period of transition from the requirement to solely use the 2015 Edition certified technology to the requirement to solely use the 2015 Edition Update certified technology. This flexibility applies to all Hospital IQR Program measures which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures.

(b) Proposed Changes to the Certification Requirements for Hybrid Measure Reporting Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination

In this proposed rule, to align with the health IT certification requirements for eCQM reporting, we are proposing to require hospitals to use only certified technology that has been updated consistent with the 2015 Edition Cures Update to submit hybrid measure data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We refer readers to our previous discussion for more detail on the proposed changes to the certification requirements for eCQMs.

We believe the 2015 Edition Cures Update will enhance interoperability and patients' access to their electronic health information, consistent with section 4006(a) of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). Health IT developers have until December 31, 2022 (the date finalized in the ONC interim final rule) to make technology certified to the updated criteria available to their customers. After this date, only certified technology updated to the 2015 Edition Cures Update will be considered certified by ONC and could be used by health care providers to report for the Hospital IQR Program if our proposals are finalized. We refer readers to section VIII.F.11.a.4. of the preamble of this proposed rule where the same proposed requirements are discussed for the Medicare Promoting Interoperability Program.

We invite public comment on our proposal, as previously discussed.

(3) Additional Submission Requirements

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), we finalized allowing hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and/or case threshold exemptions. We also finalized applying similar zero denominator declaration and case threshold exemption policies to hybrid measure reporting as we allow for eCQM reporting (84 FR 42507 through 42508).

We note that the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at 45 CFR 170.315(c)(3) to refer to CMS QRDA IGs and removes the HL7® QRDA standard requirements (85 FR 25645). We encourage all hospitals and their health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as submitting test files to the Hospital Quality Reporting (HQR) System, to allow additional time for testing and make sure all required data files are successfully submitted by the deadline.[1308] We are not proposing any changes to these policies in this proposed rule.

[1308] We recently decommissioned the Pre-Submission Validation Application (PSVA) tool within the HQR System because the system itself now performs the same functions that the PSVA tool previously did.

(4) Submission Deadlines for Hybrid Measures

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42508), where we finalized submission deadlines for hybrid measures. We are not proposing any changes to these policies in this proposed rule.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

h. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We are not proposing any changes to these policies in this proposed rule.

i. Data Submission Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 through 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 through 53539) for details on the data submission requirements for structural measures. Hospitals are required to submit information for structural measures once annually via a CMS-approved web-based data collection tool available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting system secure portal). The data submission period for structural measures begins in April until the same submission deadline as for the fourth calendar quarter of the chart-abstracted measures with respect to the reporting period for the previous calendar year. For example, for the FY 2024 payment determination, hospitals would be required to submit the required information between April 1, 2023 and May 15, 2023, with respect to the time period of January 1, 2022 through December 31, 2022.

We refer readers to section VIII.C.8.i. of the preamble of this proposed rule, where we are proposing to adopt the Maternal Morbidity Structural Measure. For the Maternal Morbidity Structural Measure and the CY 2021 reporting period/FY 2023 payment determination only, we are proposing a shortened reporting period from October 1, 2021 through December 31, 2021, while retaining the standard data submission period. Specifically, for the shortened reporting period, if our proposal is finalized as proposed, hospitals would be required to submit the data between April 1, 2022 and May 16, 2022 (we note that May 15, 2022 falls on a weekend and therefore the close of this data submission period is moved to May 16, 2022).

Thereafter, under the proposal in the VIII.C.8.i. of the preamble of this proposed rule, the reporting period for the Maternal Morbidity Structural Measure would run from: January 1 through December 31 on an annual basis, and that the data submission period would be continue to be consistent with our current policy (beginning in April until the same submission deadline as for the fourth calendar quarter of the chart-abstracted measures with respect to the reporting period for the previous calendar year).

j. Data Submission and Reporting Requirements for CDC NHSN Measures

For details on the data submission and reporting requirements for measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website.

In addition, we refer readers to section VIII.C.8.j. of the preamble of this proposed rule for more detail on our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure, which requires facilities to report data on the number of HCP who have received the full regimen of a COVID–19 vaccine through the CDC's NHSN. Specific details on data submission for this measure can be found in the CDC's Overview of the

Healthcare Safety Component, available at *https://www.cdc.gov/nhsn/PDFs/slides/NHSN-Overview-HPS_Aug2012.pdf*. For this measure, we would require reporting a single vaccination count for each healthcare facility by each individual facility's CMS Certification Number (CCN). For each CMS CCN, a percentage of the HCP who received a complete course of the COVID–19 vaccination will be calculated and publicly reported on the Care Compare website, so that the public will know what percentage of the HCP have been vaccinated in each hospital.

Consistent with our adopted policies for CDC NHSN measures in the Hospital IQR Program, hospitals will report the measure through the NHSN web-based surveillance system.[1309] Specifically, hospitals will use the COVID–19 vaccination data reporting modules in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible to have worked at the facility during the weekly submission period (denominator) and the number of those HCP who have received COVID–19 vaccination (numerator).

For the COVID–19 HCP Vaccination measure, we are proposing that hospitals would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet Hospital IQR Program requirements, beginning in October 2021 for the October 1, 2021 through December 31, 2021 reporting period affecting FY 2023 payment determination and continuing for each quarter in subsequent years. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

9. Validation of Hospital IQR Program Data

In this proposed rule, we are proposing changes to our Educational Review Process to extend the effects of the educational review policy beginning with validations affecting the FY 2024 payment determination and for subsequent years. Previously we could only correct scores for the first 3 quarters of validation due to the inability to calculate the confidence interval in a timely manner for the 4th quarter of validation. We now believe it is feasible to calculate the confidence interval and use the corrected scores identified through an educational review for all 4 quarters of validation for chart-abstracted measures. This proposal is described in detail in this section.

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 through 41608), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953) for detailed information on chart-abstracted and eCQM validation processes and previous updates to these processes for the Hospital IQR Program.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58952) where we summarized our validation policies in the following table:

	Quarters of Data Required for Validation	**Scoring**
Finalized Process for Validation Affecting the FY 2023 Payment Determination		
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020	At least 75% validation score
	4Q 2020	
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 – 4Q 2020	Successful submission of at least 75% of requested medical records
Finalized Process for Validation Affecting the FY 2024 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 – 4Q 2021	Chart-Abstracted Measures: At least 75% validation score (weighted at 100%) And eCQMs: Successful submission of at least 75% of requested medical records

[1309] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

b. Educational Review Process

(1) Chart-Abstracted Measures

(a) Background

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50260), we established an educational review process for validation of chart-abstracted measures. The process was subsequently updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38403). Under our educational review process, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation results. Approximately 4 months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Hospitals have 30 calendar days following the date validation results are posted to identify any potential CDAC or CMS errors for the first three quarters of validation results and contact the Validation Support Contractor (VSC) to request an educational review. Upon receipt of an educational review request, we review the data elements identified in the request, as well as the written justifications provided by the hospital. We provide the results of an educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through a CMS-approved secure file transmission process (82 FR 38402).

If an educational review yields incorrect validation results for chart-abstracted measures, we use the corrected quarterly score, as recalculated during the educational review process to compute the final confidence interval (82 FR 38402). We use the revised score identified through an educational review when determining whether or not a hospital failed validation (82 FR 38402). Corrected scores, however, are only used if they indicate that the hospital performed more favorably than previously determined (82 FR 38402). We note that corrections only occur to calculations, not to the underlying measure data (82 FR 38402). Under the current policy, for the last quarter of validation for chart-abstracted measures, because of the need to calculate the confidence interval in a timely manner and the insufficient time available to conduct educational reviews, no educational reviews are available (82 FR 38403). The existing reconsideration process would be used to dispute an unsatisfactory validation result.

In the FY 2021 IPPS/LTCH PPS final rule, we finalized several policies to incrementally align the validation processes for chart-abstracted measure data and eCQM data in a stepwise process in the Hospital IQR Program (85 FR 58942 through 58952). As part of this policy, we updated the quarters of data required for validation for both chart-abstracted measures and eCQMs as summarized in these charts:

Previously Finalized Quarters Required for Validation Affecting FY 2023 Payment Determination (These quarters have been updated, as shown in the subsequent tables)		
Measures Submitted	**Required Quarters of Data for Validation**	**Validation Data Request Timeframe**
Chart-Abstracted Measures	3Q 2020	4Q 2020 – 1Q 2021
	4Q 2020	1Q – 2Q 2021
	1Q 2021	2Q-3Q 2021
	2Q 2021	3Q -4Q 2021
eCQMs	1Q 2020 - 4Q 2020	2Q – 3Q 2021

Current Quarters Required for Validation Affecting the FY 2023 Payment Determination	
Measures Submitted	**Required Quarters of Data for Validation**
Chart-Abstracted Measures	3Q 2020
	4Q 2020
eCQMs	1Q 2020 - 4Q 2020

Current Quarters Required for Validation Affecting the FY 2024 Payment Determination	
Measures Submitted	**Required Quarters of Data for Validation**
Chart-Abstracted Measures	1Q 2021
	2Q 2021
	3Q 2021
	4Q 2021
eCQMs	1Q 2021 - 4Q 2021

(b) Proposal To Extend the Effects of the Educational Review Policy Beginning With Validations Affecting the FY 2024 Payment Determination and Subsequent Years

In light of the most recently finalized quarters included in validation, we are proposing to extend the effects of the educational review policy beginning with validations affecting the FY 2024 payment determination and for subsequent years. As previously noted, in the past we could only correct scores for the first three quarters of validation due to the inability to calculate the confidence interval in a timely manner for the 4th quarter of validation. We now believe it is feasible to calculate the confidence interval and use the corrected scores identified through an educational review for all four quarters of validation for chart-abstracted measures, because the quarters used for validation are now early enough to calculate the confidence interval for the fourth quarter of validation in a timely manner. Specifically, under our previous policy, the quarters used for validation for the FY 2024 payment determination would have been 3Q 2021, 4Q 2021, 1Q 2022 and 2Q 2022. Under the most recently finalized policy, the quarters used for validation for the FY 2024 payment determination are 1Q 2021, 2Q 2021, 3Q 2021, and 4Q 2021. Therefore, we propose to extend the effects of educational reviews for 4th quarter data such that if an error is identified during the education review process for 4th quarter data, we would use the corrected quarterly score to compute the final confidence interval used for payment determination.

All previously finalized policies with respect to education reviews would apply, such that approximately four months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Hospitals have 30 calendar days following the date validation results are posted to identify any potential CDAC or CMS errors for the first three quarters of validation results and contact the Validation Support Contractor (VSC) to request an educational review. Upon receipt of an educational review request, we review the data elements identified in the request, as well as the written justifications provided by the hospital. We provide the results of an educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through a CMS-approved secure file transmission process (82 FR 38402). If an educational review yields incorrect validation results for chart-abstracted measures, we use the corrected quarterly score, as recalculated during the educational review process to compute the final confidence interval (82 FR 38402). We use the revised score identified through an educational review when determining whether or not a hospital failed validation (82 FR 38402). Corrected scores, however, are only used if they indicate that the hospital performed more favorably than previously determined (82 FR 38402). We note that corrections only occur to calculations, not to the underlying measure data (82 FR 38402). We also note that under this proposal, as is currently the process, the quarterly validation reports for the chart-abstracted measures validation issued to hospitals would not be changed to reflect the updated score due to the burden associated with reissuing corrected reports (82 FR 38402).

In addition, this proposal does not apply to the educational review process for eCQMs, which is discussed in the next section.

We invite public comment on our proposal, as previously discussed.

(2) Educational Review Process for eCQMs for Validation Affecting the FY 2023 Payment Determination and Subsequent Years

We refer readers to the FY 2021 IPPS/LTCH PPS (85 FR 58953) final rule where we finalized an educational review process for eCQM validation beginning with validations affecting the FY 2023 payment determination and for subsequent years (that is, starting with data from CY 2020). Under that process, hospitals receive eCQM validation results on an annual basis, and have the opportunity to request an educational review once annually following receipt of their results (85 FR 58953). We are not proposing any changes to these policies in this proposed rule.

10. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We are not proposing any changes to this policy in this proposed rule.

11. Public Display Requirements

a. Background

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Care Compare website, or its successor

website, after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58953) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Care Compare* website at *https://www.medicare.gov/care-compare*, or on other CMS websites such as: *medicare.gov/care-compare*. We are not proposing any changes to these policies in this proposed rule.

b. Public Reporting of eCQM Data

We direct readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58954 through 58959) where we finalized public reporting requirements of eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. We note that this policy incrementally increases the eCQM data publicly reported to four quarters of data for the CY 2023 reporting period/FY 2025 payment determination and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

c. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings will utilize data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital IQR Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule with comment period for details.

We are not proposing any changes to these policies in this proposed rule.

12. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not proposing any changes to these policies in this proposed rule.

13. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *http://www.QualityNet.cms.gov* for our current requirements for submission of a request for an exception. We are not proposing any changes to these policies in this proposed rule.

D. Proposed Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act and applies to hospitals described in section 1866(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50853);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50286);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624);
- The CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524); and
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58959 through 58966).

2. Overview of Proposed Updates to the PCHQR Program and Requests for Information

In section IX.D.4. of this proposed rule, we are proposing to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) measure beginning with the FY 2024 program year. In section IX.D.5. of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the FY 2023 program year and for subsequent years. In section I.X.D.9. of this proposed rule, we are proposing to update our terminology for this program by replacing the term ''QualityNet Administrator'' with ''QualityNet security official.'' In section IX.D.11. of this proposed rule, we are proposing to codify existing PCHQR Program policies at 42 CFR 412.23(f)(3) and 42 CFR 412.24.

We also refer readers to section IX.B of this proposed rule, Closing the Health Equity Gap in CMS Quality Programs—A Request for Information, where we request information on our Equity Plan for Improving Quality in Medicare, which outlines our commitment to closing the health equity gap through improved data collection in order to better measure and analyze disparities across programs and policies. The request for information asks for public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital equity score in CMS quality reporting and value-based purchasing programs, including the PCHQR Program.

We also refer readers to section IX.A. of this proposed rule where we request information on potential actions we can take to expand the use of the FHIR standard (as described in that section) in furtherance of our goal to move fully to digital quality measurement in CMS quality reporting programs, including the PCHQR Program, and value-based purchasing programs by 2025.

3. Measure Retention and Removal Factors for the PCHQR Program

For a detailed discussion regarding our retention and removal factors, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), where we adopted policies for measure retention and removal, and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611), where we updated our measure removal factors. We are not proposing any changes to these policies in this proposed rule.

4. Proposed Removal of the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) Measure From the PCHQR Program Beginning With the FY 2024 Program Year

We are proposing to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) (''Oncology: Plan of Care for Pain'') measure from the PCHQR Program beginning with the FY 2024 program year based on Factor-7: *It is not feasible to implement the measure specifications.* We first adopted the Oncology: Plan of Care for Pain measure for the FY 2016 program year in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50842 through 50843) and we refer readers to this rule for a detailed discussion of the measure. Although we continue to believe the Oncology: Plan of Care for Pain measure provides important data for patients and hospitals in making decisions about care and informing quality improvement efforts, the measure steward has decided to revert to a previous version of the measure that requires a plan of care to address any, rather than just moderate-severe, pain and will no longer maintain the specifications for this measure as it is currently used in the PCHQR Program. In addition, the version of the measure that the measure steward has decided to revert to is designed to be paired with the *Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384)* measure (78 FR 50843), meaning they were developed to be used together (77 FR 53649). The *Medical and Radiation—Pain Intensity Quantified (PCH–16/NQF #0384)* measure was removed from the PCHQR Program's measure set beginning with the FY 2021 program year in the FY 2019 IPPS/LTCH PPS final rule because it was topped-out (83 FR 41611 through 41613).

Through our Meaningful Measures Initiative, we continue to focus on proposing quality measures that will reduce reporting and regulatory burden on providers and accelerate the move to fully digital measures.[1310] In the FY 2014 IPPSLTCH PPS final rule, we stated our intention to simplify measure collection and submission, and to reduce the reporting burden of chart-abstracted measures (78 FR 50810). PCH–15 requires manual chart-abstraction, and we believe this proposal to remove it is aligned with the goals of the Meaningful Measures Initiative and a shift toward the use of digital quality measures.

Further, the PCH–15 measure's mean and median for the past four years, including FY 2020, demonstrate very high performance with little variation among the 11 PCHs. Accordingly, because the version of the Oncology: Plan of Care for Pain measure that is currently used in the PCHQR Program will no longer be maintained by the measure steward, data show high performance on the measure with little variation, the updated version of the measure is designed to be used with the PCH–16 measure that we previously removed because it was topped-out, and the removal of chart-abstracted measures aligns with CMS goals to move to digital quality measures, we are proposing to remove the Oncology: Plan of Care for Pain measure from the PCHQR measure set.

We invite public comment on our proposal to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383) (PCH–15) measure from the PCHQR Program beginning with the FY 2024 program year.

5. Proposal To Adopt the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the FY 2023 Program Year

a. Background

On January 31, 2020, the Secretary declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[1311] COVID–19 is a contagious respiratory illness [1312] that can cause serious illness and death. Older individuals, racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[1313] [1314]

As of April 2, 2021, the U.S. has reported over 30 million cases of COVID–19 and over 550,000 COVID–19 deaths.[1315] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[1316] From December 2, 2020 to January 30, 2021, more than 100,000 Americans were in the hospital with COVID–19 at the same time.[1317]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[1318] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[1319] Thus, the CDC advises that infections mainly occur through exposure to respiratory droplets when a person is in close contact with someone who has COVID–19.[1320],[1321] Although less common, COVID–19 can also spread when individuals are not in close contact if small droplets or particles containing the virus linger in the air after the person who is infected as left the space.[1322] Another means of less common transmission is contact with a contaminated surface.[1323] According to the CDC, those at greatest risk of

[1310] CMS List of Measures under Consideration for December 21, 2020. Accessed March 12, 2021. *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf.*

[1311] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[1312] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[1313] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[1314] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[1315] Centers for Disease Control and Prevention. (2021). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[1316] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[1317] US Currently Hospitalized √ The COVID Tracking Project. *Accessed January 31, 2021 at: https://covidtracking.com/data/charts/us-currently-hospitalized.*

[1318] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1319] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1320] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1321] Centers for Disease Control and Prevention (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1322] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

[1323] Centers for Disease Control and Prevention. (2021). How COVID–19 Spreads. Accessed on April 3, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html.*

infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed COVID–19 infection, regardless of whether the individual has symptoms.[1324] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between health care personnel (HCP) and patients given the close contact that may occur during the provision of care.[1325] The CDC has emphasized that health care settings, including long-term care settings, can be high-risk places for COVID–19 exposure and transmission.[1326]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[1327] On December 11, 2020, the FDA issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[1328] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines.[1329] [1330]

As part of its national strategy to address COVID–19, the Biden Administration stated on March 25, 2021 that it would work with states and the private sector to execute an aggressive vaccination strategy and outlined a goal of administering 200 million shots in 100 days.[1331] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including HCP providing direct care to patients with COVID–19, and individuals at highest risk for developing severe illness from COVID–19.[1332] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccine, given the potential for transmission in health care settings and the need to preserve health care system capacity.[1333] Research suggests most states followed this recommendation,[1334] and HCP began receiving the vaccine in mid-December of 2020.[1335]

Frontline healthcare workers, such as those employed in PCHs, are being prioritized for vaccination in most locations. There are approximately 18 million healthcare workers in the United States.[1336] As of April 3, 2021, the CDC reported that over 162 million doses of COVID–19 vaccine had been administered, and approximately 60 million people had received full doses.[1337] President Biden indicated on April 6, 2021 that the United States has sufficient vaccine supply to make every adult eligible to receive a vaccine beginning April 19, 2021.[1338]

We believe it is important to require that PCHs report their rates of HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, and to help sustain the ability of U.S. hospitals to continue serving their communities throughout the PHE and beyond. Therefore, we are proposing a new measure, COVID–19 Vaccination Coverage Among HCP (COVID–19 vaccination measure), beginning with the FY 2023 program year. For that program year, PCHs would be required to report data on the measure for the fourth quarter of CY 2021 (that is, from October 2021 through December 2021). For more information about the proposed reporting period, see section IX.D.5.c. of this proposed rule. The measure will assess the proportion of a PCH's HCP that has been vaccinated against COVID–19.

Although data showing the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS–CoV–2 are limited at this time, we believe PCHs should report their rates of vaccination among their HCP as part of their efforts to assess and reduce the risk of transmission of COVID–19. HCP vaccination can potentially reduce illness that leads to work absence and limit disruptions to care.[1339] Data from influenza vaccination demonstrates that provider uptake of the vaccine is also associated with that provider recommending vaccination to patients,[1340] and we believe HCP COVID–19 vaccination in PCHs could similarly increase uptake among that patient population. We also believe that publishing the HCP vaccination rates will be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose PCHs from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 HCP vaccination measure

[1324] Centers for Disease Control and Prevention. (2021). When to Quarantine. Accessed on April 2, 2021 at: *https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html*.

[1325] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on April 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Transmission*.

[1326] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[1327] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1328] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download*.

[1329] U.S. Food and Drug Administration. (2021). Moderna COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[1330] U.S. Food and Drug Administration. (2021). Janssen COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[1331] The White House. Remarks by President Biden in Press Conference. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/25/remarks-by-president-biden-in-press-conference/*.

[1332] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1333] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[1334] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[1335] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

[1336] Centers for Disease Control and Prevention. Healthcare Workers. (2017) Accessed February 18, 2021 at: *https://www.cdc.gov/niosh/topics/healthcare/default.html*.

[1337] Centers for Disease Control and Prevention. COVID Data Tracker. COVID–19 Vaccinations in the United States. (2021) Accessed February 18, 2021 at: *https://covid.cdc.gov/covid-data-tracker/#vaccinations*.

[1338] The White House. Remarks by President Biden Marking the 150 Millionth COVID–19 Vaccine Shot. Accessed April 8, 2021 at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/04/06/remarks-by-president-biden-marking-the-150-millionth-covid-19-vaccine-shot/*.

[1339] Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel. October 2020. (2020) Accessed March 16, 2021 at: *https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*.

[1340] Measure Application Committee Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

addresses the quality priority of ''Promote Effective Prevention and Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

b. Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure (''COVID–19 HCP vaccination measure'') is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in non-long-term care facilities such as PCHs.

(1) Measure Specifications

The denominator is the number of HCP eligible to work in the PCH for at least one day during the reporting period (as described in section IX.D.5.c.), excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[1341]

The numerator is the cumulative number of HCP eligible to work in the PCH for at least one day during the reporting period (as described in section IX.D.5.c.) and who received a complete vaccination course against COVID–19 using an FDA-authorized vaccine for COVID–19 (whether the FDA issued an approval or EUA). A complete vaccination course is defined under the specific FDA authorization (either the EUA or the approval) and may require multiple doses or regular revaccination.[1342] Vaccination coverage is defined, for purposes of this measure, as the percentage of HCP eligible to work at the PCH for at least one day who received a complete vaccination course against COVID–19. The proposed specifications for this measure are available at *https://www.cdc.gov/nhsn/nqf/index.html*.

(2) Review by the Measure Applications Partnership (MAP)

The COVID–19 HCP vaccination measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020,'' [1343] a list of measures under consideration for use in various Medicare programs. When the Measure Applications Partnership (MAP) Hospital Workgroup convened on January 11, 2021, it reviewed the measures on the MUC List, including the COVID–19 HCP vaccination measure. The MAP Hospital Workgroup recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the PCHQR Program measure set by providing transparency about an important COVID–19 intervention to help prevent infections in HCP and patients.[1344] The MAP Hospital Workgroup also stated that collecting information on COVID–19 vaccination coverage among HCP and providing feedback to PCHs will allow PCHs to benchmark vaccine coverage rates and improve their vaccine coverage rates, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[1345]

In its preliminary recommendations, the MAP Hospital Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[1346] To mitigate its concerns, the MAP Hospital Workgroup believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[1347] Subsequently, the MAP Coordinating Committee met on January 25, 2021 and reviewed the COVID–19 Vaccination Coverage Among HCP measure. In the 2020–2021 MAP Final Recommendations issued March 11, 2021, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications are further refined, specifically saying that ''the incomplete specifications require immediate mitigation and further development should continue.'' [1348] In its final report, the MAP noted that the measure would add value to the program measure set by providing visibility into an important intervention to limit COVID–19 infections in healthcare personnel and the patients for whom they provide care.[1349]

In response to the MAP final recommendation request that CMS bring the measure back to the MAP once the specifications are further refined, CMS and the CDC met with the MAP Coordinating Committee on March 15th. CMS and the CDC provided additional information to the MAP Coordinating Committee at that meeting that addressed vaccine availability, the alignment of the COVID–19 vaccination measure specifications as closely as possible with the Influenza HCP vaccination measure (NQF 0431) specifications, and the definition of HCP used in the measure. At this meeting, CMS and the CDC also presented preliminary findings from the testing of the numerator of COVID–19 Vaccination Coverage Among HCP, which is currently in process. These preliminary findings showed that the numerator data should be feasible and reliable. Testing of the numerator of the number of healthcare personnel vaccinated involves a comparison of vaccination data collected by the CDC directly from long-term care facilities (LTCs) through NHSN with vaccination data independently reported to the CDC through the Federal pharmacy partnership program. These are two completely independent data collection systems. In initial analyses of the first month of vaccination from December 2020 to January 2021, of HCP vaccination in approximately 1,200 facilities which reported to both systems, the number of healthcare personnel vaccinated was highly correlated between these 2 systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting.[1350] Because of the high correlation across a large number of facilities and high number of HCP within those facilities receiving at least

[1341] Centers for Disease Control and Prevention. Contraindications and precautions. (2021) Accessed March 15, 2021 at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Contraindications*.

[1342] Measure Application Partnership Coordinating Committee Meeting Presentation. March 15, 2021. (2021) Accessed March 16, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*.

[1343] The National Quality Forum. (2021) Accessed March 14, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94212*.

[1344] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on January 24, 2021 at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[1345] *Ibid.*

[1346] *Ibid.*

[1347] *Ibid.*

[1348] Measure Applications Partnership. 2020–2021 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on March 12, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[1349] Measure Applications Partnership. 2020–2021 Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Accessed on March 12, 2021 at: *https://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[1350] For more information on testing results and other measure updates, please see the Meeting Materials (including Agenda, Recording, Presentation Slides, Summary, and Transcript) of the March 15, 2021 meeting available at: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*; Gharpure R, Guo A, Bishnoi CK, et al. Early COVID–19 First-Dose Vaccination Coverage Among Residents and Staff Members of Skilled Nursing Facilities Participating in the Pharmacy Partnership for Long-Term Care Program—United States, December 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:178–182. DOI: *http://dx.doi.org/10.15585/mmwr.mm7005e2*.

one dose of the COVID–19 vaccine, we believe these data indicates the measure is feasible and reliable for use in PCHs.

We value the recommendations of the MAP and considered these recommendations carefully. Section 1890A(a)(4) of the Act requires the Secretary to take into consideration input from multi-stakeholder groups in selecting quality and efficiency measures. While we value input from the MAP, we believe it is important to propose the measure as quickly as possible to address the urgency of the COVID–19 PHE and its impact on PCHs and the vulnerable populations they serve. CMS continues to engage with the MAP to mitigate its concerns and appreciates the MAP's conditional support for the measure.

(3) NQF Endorsement

Section 1866(k)(3)(A) of the Act states that subject to subparagraph (B), any measure specified by the Secretary for the PCHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act. The National Quality Forum (NQF) currently holds this contract. Under section 1866(k)(3)(B), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed COVID–19 Vaccination Coverage Among HCP measure is not NQF endorsed and has not been submitted to NQF for endorsement consideration.

Because this measure is not NQF-endorsed, we considered whether there are other available measures that assess COVID–19 vaccination rates among HCP. We found no other feasible and practical measures on the topic of COVID–19 vaccination among HCP, therefore the exception in section 1866(k)(3)(B) of the Act applies.

c. Data Collection, Submission and Reporting

Given the time sensitive nature of this measure considering the current PHE, we are proposing that for the FY 2023 program year, the reporting period for the proposed COVID–19 Vaccination Coverage Among HCP measure would be from October 1, 2021 through December 31, 2021. Thereafter, we propose quarterly reporting deadlines for the PCHQR Program. If our proposal to adopt this measure is finalized, PCHs would report the measure through the NHSN web-based surveillance system.[1351] PCHs currently use the NHSN web-based system to report five HAI measures for the PCHQR Program, as well as the Influenza Vaccination Coverage Among HCP (NQF #0431).

To report this measure, we are proposing that PCHs would collect the numerator and denominator for the COVID–19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline to meet PCHQR Program requirements. While we believe that it would be ideal to have HCP vaccination data for every week of each month, we are mindful of the time and resources that PCHs would need to report the data. Thus, in collaboration with the CDC, we determined that data from at least one week of each month would be sufficient to obtain a reliable snapshot of vaccination levels among a PCH's healthcare personnel while balancing the costs of reporting. If a PCH submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, third week data would be used. If first, second, and fourth week data are submitted, fourth week data would be used. Each quarter, we are proposing that the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each PCH, which would be calculated by taking the average of the data from the three weekly rates submitted by the PCH for that quarter. If finalized, CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC.

As described in section IX.D.5.b.(1)., PCHs would report the number of HCP eligible to have worked at the facility during the self-selected week that the PCH reports data for in NHSN (denominator) and the number of those HCP who have received a complete course of a COVID–19 vaccination (numerator) during the same self-selected week.

We invite public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage Among HCP, to the PCHQR Program beginning with the FY 2023 program year, with a October 1, 2021 through December 31, 2021 reporting period for that program year, and continuing with quarterly reporting deadlines for subsequent PCHQR Program years.

6. Summary of PCHQR Program Measures for the FY 2023 Program Year and Subsequent Years

This table summarizes the PCHQR Program measure set for the FY 2023 program year and subsequent years if our proposal to adopt the COVID–19 Vaccination Coverage Among HCP measure is finalized.

[1351] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

FY 2023 PCHQR Program Measure Set and Subsequent Years

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
COVID-19 HCP Vaccination	N/A	COVID-19 Vaccination Coverage Among HCP*
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
N/A	0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology**
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer

* Measure proposed for adoption beginning with FY 2023.

** Measure proposed for removal beginning with FY 2024.

7. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at: *https://qualitynet.cms.gov/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy to use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We are not proposing any changes to our processes for maintaining technical specifications for PCHQR Program measures.

8. Public Display Requirements

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. For additional information regarding previously finalized public display requirements and policies, we refer readers to previous final rules.

In the table that follows, we summarize our current public display requirements for the PCHQR Program measures. The PCHQR measures' performance data is made publicly available on a CMS website, which is currently the Provider Data Catalog, available at: *https://data.cms.gov/provider-data/*. We are not proposing any changes to these public display requirements.

Finalized Public Display Requirements for PCHQR Program

Summary of Finalized Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (NQF #0166) • Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)*	2016 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) • National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	2019 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years
• CAUTI (NQF #0138) • CLABSI (NQF #0139)	Deferred until CY 2022

**Measure proposed for removal, beginning with the FY 2024 program year.*

9. Form, Manner, and Timing of Data Submissions

a. Procedural Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53567) for our previously finalized procedural requirements for the PCHQR Program. Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website.

b. Proposal To Update Reference to QualityNet Administrator

Under our current procedural requirements, each PCH that participates in the PCHQR Program must identify one or more QualityNet Administrators who will follow the registration process located on the QualityNet website (*https://qualitynet.cms.gov*) (77 FR 53563).

In this proposed rule, we propose to use the term ''QualityNet security official'' instead of ''QualityNet Administrator'' to align with the terminology we use or are proposing to use in other quality reporting programs. This proposed update in terminology would not change the individual's responsibilities or add burden.

Additionally, we are clarifying that failing to maintain an active QualityNet security official once a PCH has successfully registered to participate in the PCHQR Program will not result in a finding that the PCH did not successfully participate in the PCHQR Program.

We invite public comment on our proposal to replace the term ''QualityNet administrator'' with ''QualityNet security official.''

10. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We are not proposing any changes to this policy.

11. Proposal To Codify PCHQR Program Requirements at New 42 CFR 412.23(f) and New 42 CFR 412.24 of Our Regulations

There are currently no codified PCHQR Program requirements in our regulations. Accordingly, as we have done with a number of other CMS quality reporting programs, we are proposing to add a new section at 42 CFR 412.24 entitled, ''Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program'' that codifies the program requirements listed in this proposed rule and a new paragraph (3) to 42 CFR 412.23(f) that requires cancer hospitals that participate in the PCHQR Program to follow all such program requirements. We believe that the codification of these requirements will make it easier for stakeholders to find these requirements.

Specifically, we propose to amend 42 CFR 412.23(f) by adding a new paragraph (3) that requires cancer hospitals, as classified under that paragraph, participating in the PCHQR Program to follow all requirements listed in the new section 42 CFR 412.24.

We also propose to add a new section at 42 CFR 412.24 that contains the regulations that govern the PCHQR Program:

- Program participation requirements (adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563)) including the PCHQR Program registration process;
- Data submission requirements for quality measures (adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563)) that are selected by CMS under section 1866(k) of the Act and must be submitted in a form and manner, and at a time, specified by CMS;
- Quality measure removal and retention factors (adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183) and expanded in FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611));
- Public reporting requirements for quality measure data reported by PCHs, with measure information displayed on the CMS website (adopted in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191)), and
- Our extraordinary circumstances exception policy (adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848) and updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38424 through 38425)) detailing the process for CMS to grant an extension or exception to quality measure reporting requirements under the PCHQR Program.

We welcome public comment on the proposed codification of these existing PCHQR Program policies.

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the background for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42524 through 42591). For more information on the requirements under the LTCH QRP, we refer readers to 42 CFR 412.560.

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2022 LTCH QRP

The LTCH QRP currently has 17 measures for the FY 2022 LTCH QRP, which are set out in the following IX.E.-01. For a discussion of the factors used to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to FY 2019 IPPS/LTCH PPS Final Rule (83 FR 41624 through 41634) and to the regulations at 42 CFR 412.560(b)(3).

Table IX.E.-01. Quality Measures Currently Adopted for the FY 2022 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Application of Functional Assessment/ Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH–Provider*	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH–Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC)

Short Name	Measure Name & Data Source
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717)
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3562)
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP) (NQF #3480)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

*In response to the COVID-19 public health emergency (PHE), CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the Transfer of Health Information measures for at least one full fiscal year after the end of the PHE.

4. LTCH QRP Quality Measure Proposals Beginning With the FY 2023 LTCH QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) or (d)(1) of the Act respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension, or addition. We propose to adopt one new measure, the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) [1352] measure as an ''other'' measure under section 1899B(d)(1) of the Act beginning with the FY 2023 LTCH QRP. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure are standardized and interoperable. The proposed measure supports the Meaningful Measures domain of Promote Effective Prevention and Treatment of Chronic Disease. CMS identified the measure concept as a priority in response to the current public health crisis. This process measure was developed with the Centers for Disease Control and Prevention (CDC) to track COVID–19 vaccination coverage among HCP in the LTCH setting. This measure is described in more detail below.

In addition, we propose to update the denominator for one measure, the Transfer of Health (TOH) Information to the Patient–Post-Acute Care (PAC) measure to exclude patients discharged home under the care of an organized home health service or hospice.

a. Proposed COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) Measure Beginning with the FY 2023 LTCH QRP

(1) Background

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS-CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[1353] COVID–19 is a contagious respiratory infection [1354] that can cause serious illness and death. Older individuals, racial and ethnic

[1352] The measure steward changed the name of the measure from SARS-CoV–2 Vaccination Coverage among Healthcare Personnel to COVID–19 Vaccination Coverage among Healthcare Personnel. There were no changes to the measure itself, other than the name change.

[1353] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[1354] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

minorities,[1355] and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[1356] As of April 10, 2021, the U.S. reported over 30 million cases of COVID–19 and over 558,000 COVID–19 deaths.[1357] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[1358] In December 2020 and January 2021, media outlets reported that more than 100,000 Americans were in the hospital with COVID–19.[1359]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[1360] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[1361] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [1362] and is not thought to be a common way that COVID–19 spreads, and that in certain circumstances, infection can occur through airborne transmission.[1363] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS–CoV–2 infection, regardless of whether the individual has symptoms.[1364] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in healthcare settings, COVID–19 can spread between healthcare personnel (HCP) and patients given the close contact that may occur during the provision of care.[1365] The CDC has emphasized that healthcare settings, including LTCHs, can be high-risk places for COVID–19 exposure and transmission.[1366] Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[1367]

On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[1368] Subsequently the FDA issued EUAs for additional COVID–19 vaccines. In issuing these EUAs, the FDA determined that it was reasonable to conclude that the known and potential benefits of each vaccine, when used as authorized to prevent COVID–19, outweighed its known and potential risks.[1369] [1370] [1371]

As part of its national strategy to address COVID–19, the current administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[1372] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including healthcare personnel (HCP), and individuals at highest risk for developing severe illness from COVID–19.[1373] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in healthcare settings and the need to preserve healthcare system capacity.[1374] Research suggests most states followed this recommendation,[1375] and HCP began receiving the vaccine in mid-December of 2020.[1376]

HCP are at risk of carrying COVID–19 infection to patients, experiencing

[1355] Centers for Disease Control and Prevention. (2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html*.

[1356] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html*.

[1357] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at: *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days*.

[1358] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895*. Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at: *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html*.

[1359] NPR. U.S. Hits 100,000 COVID–19 Hospitalizations, Breaks Daily Death Record. Dec. 2, 2020. Accessed on December 17, 2020 at *https://www.npr.org/sections/coronavirus-live-updates/2020/12/02/941902471/u-s-hits-100–000-covid-19-hospitalizations-breaks-daily-death-record*; The Wall Street Journal. Coronavirus Live Updates: U.S. Hospitalizations, Newly Reported Cases, Deaths Edge Downward. Accessed on January 11 at *https://www.wsj.com/livecoverage/covid-2021-01-11*.

[1360] Centers for Disease Control and Prevention. (2021). COVID–19. Your Health. Frequently Asked Questions. *Accessed on January 11, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html*.

[1361] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. *Accessed on January 11, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html*.

[1362] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. *Accessed on January 11, 2021 at: https://www.cdc.gov/coronavirus/2019-ncov/faq.html*.

[1363] Centers for Disease Control and Prevention. (2020). Centers for Disease Control Scientific Brief: SARS-CoV–2 and Potential Airborne Transmission. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html*.

[1364] Centers for Disease Control and Prevention. (2020). Clinical Questions about COVID–19: Questions and Answers. Accessed on December 2, 2020 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html*.

[1365] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on December 2 at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html*.

[1366] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[1367] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1368] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. *Available* at *https://www.fda.gov/media/144412/download*.

[1369] Ibid.

[1370] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download*.

[1371] U.S. Food and Drug Administration (2020). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download*.

[1372] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at: *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/*.

[1373] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at: *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf*; Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at: *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf*.

[1374] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[1375] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/*.

[1376] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at: *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f*.

illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe it is important to require that LTCHs report COVID–19 HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond.

We also believe that publishing facility-level COVID–19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under the Meaningful Measures framework, the COVID–19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of ''Promote Effective Prevention & Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

Therefore, we are proposing a new measure, COVID–19 Vaccination Coverage among HCP to assess the proportion of an LTCH's healthcare workforce that has been vaccinated against COVID–19.

(2) Stakeholder Input

In our development and specification of the measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act.[1377] To meet this requirement, the following opportunity was provided for stakeholder input.

The pre-rule making process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List that the Secretary is considering adopting, through Federal rulemaking process, for use in Medicare program(s). This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The COVID–19 Vaccination Coverage among Healthcare Personnel measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List).[1378] Five comments were received from industry stakeholders during the pre-rulemaking process on the COVID–19 Vaccination Coverage among HCP measure, and support was mixed. Commenters generally supported the concept of the measure. However, there was concern about the availability of the vaccine and measure definition for HCP, and some commenters encouraged CMS to continue to update the measure as new evidence comes in.

(3) Measure Applications Partnership (MAP) Review

When the Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID–19 Vaccination Coverage among HCP measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the LTCH QRP measure set by providing transparency about an important COVID–19 intervention to help limit COVID–19 infections.[1379] The MAP also stated that collecting information on COVID–19 vaccination coverage among healthcare personnel and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[1380]

In its preliminary recommendations, the MAP PAC–LTC Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[1381] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[1382] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage among Healthcare Personnel measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measures back to MAP once the specifications are further clarified. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

In response to the MAP request for CMS to bring the measure back once the specifications were further clarified, CMS met with the MAP Coordinating Committee on March 15, 2021. First, CMS and CDC clarified the alignment of the COVID–19 Vaccination Coverage among HCP with the Influenza Vaccination Coverage among HCP (NQF #0431), an NQF-endorsed measure since 2012. The COVID–19 Vaccination Coverage among HCP measure is calculated using the same approach as the Influenza Vaccination Coverage among HCP measure.[1383] The approach to identifying HCPs eligible for the COVID–19 vaccination is analogous to those used in the NQF endorsed flu measure which underwent rigorous review from technical experts about the validity of that approach and for which ultimately received NQF endorsement. More recently, prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized COVID–19 vaccines are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of vaccines was 90%.[1384]

Additionally, to support the measure's data element validity, the CDC conducted testing of the COVID–19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination for approximately 1,200 facilities that had data from both systems, the number of HCP vaccinated was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two

[1377] Centers for Medicare & Medicaid Services. Pre-rulemaking. Accessed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking*.

[1378] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at: *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

[1379] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on February 3, 2021 at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650*.

[1380] Ibid.

[1381] Ibid.

[1382] Ibid.

[1383] The Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

[1384] Centers for Disease Control and Preventions. Morbidity and Mortality Weekly Report. March 29, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w*.

weeks of reporting. Of note, assessment of data element reliability may not be required by NQF if data element validity is demonstrated.[1385] To assess the validity of new performance measure score (in the case, percentage of COVID–19 vaccination coverage), NQF allows assessment by face validity (that is, subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process),[1386] and the MAP concurred with the face validity of the COVID–19 Vaccination Coverage among HCP measure. Materials from the March 15, 2021 MAP Coordinating Committee meeting can be found on the NQF website here: *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

This measure is not NQF endorsed, but the CDC, in collaboration with CMS, plans to submit the measure for NQF endorsement in the future.

(4) Competing and Related Measures

Section 1886(m)(5)(D)(i) of the Act requires that absent an exception under section 1886(m)(5)(D)(ii) of the Act, measures specified under section 1886(m)(5)(D) of the Act be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1886(m)(5)(D)(ii) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Section 1899B(e)(2)(A) of the Act requires that, subject to section 1899B(e)(2)(B) of the Act, each measure specified by the Secretary under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a) of the Act. However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The proposed COVID–19 Vaccination Coverage among HCP measure is not currently NQF endorsed and has not been submitted to the NQF for consideration, so we considered whether there are other available measures that assess COVID–19 vaccinations among HCP. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF-endorsed measures for LTCHs focused on capturing COVID–19 vaccination coverage among HCP, and we found no other feasible and practical measure on the topic of COVID–19 vaccination coverage among HCP. The only other vaccination coverage of HCP measure we found was the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

Given the novel nature of the SARS-CoV–2 virus, and the significant and immediate risk it poses in LTCHs, we believe it is necessary to propose the measure as soon as possible. Therefore, after consideration of other available measures that assess COVID–19 vaccination rates among HCP, we believe the exception under section 1899B(e)(2)(B) of the Act applies. This proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among LTCH providers.

(5) Quality Measure Calculation

The COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as LTCHs. Since this proposed measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The denominator would be the number of HCP eligible to work in the LTCH for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination described by the CDC.[1387]

The numerator would be the cumulative number of HCP eligible to work in the LTCH for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV–2. A complete vaccination course may require one or more doses depending on the specific vaccine used. The finalized measure specifications can be found on the CDC website here: *https://www.cdc.gov/nhsn/nqf/index.html*.

We propose that LTCHs would submit data for the measure through the CDC/NHSN data collection and submission framework.[1388] This framework is currently used for reporting the CAUTI (NQF #0318) and Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measures. LTCHs would use the COVID–19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible who have worked at the facility that week (denominator) and the number of those HCP who have received a completed COVID–19 vaccination course (numerator). LTCHs would submit COVID–19 vaccination data for at least one week each month. If LTCHs submit more than one week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the three monthly modules reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. Subsequent to the first refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data on Care Compare.

For purposes of submitting data to CMS for the FY 2023 LTCH QRP, LTCHs would be required to submit data for the period October 1, 2021 through December 31, 2021. Following the initial data submission quarter for the FY 2023 LTCH QRP, subsequent compliance for the LTCH QRP would be based on a full calendar year of data submission. For more information on the measure's proposed public reporting period, we refer readers to section E.9.d. of this proposed rule.

We invite public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among Healthcare Personnel, to the LTCH QRP beginning with the FY 2023 LTCH QRP.

[1385] National Quality Form. Key Points for Evaluating Scientific Acceptability. Revised January 3, 2020. *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx#:~:text=NQF%20is%20not%20prescriptive%20about,reliability%20or%20validity%20testing%20results.&text=Reliability%20and%20validity%20must%20be,source%20and%20level%20of%20analysis*).

[1386] Ibid.

[1387] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United Sates. Accessed at: *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html*.

[1388] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

b. Proposed Update to the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure Beginning With the FY 2023 LTCH QRP

We are proposing to update the Transfer of Health Information to the Patient—Post-Acute Care (PAC) measure denominator to exclude patients discharged home under the care of an organized home health service or hospice. This measure assesses for and reports on the timely transfer of health information, specifically transfer of a medication list. We adopted this measure in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42525 through 42535) beginning with the FY 2022 LTCH QRP. It is a process-based measure that evaluates the transfer of information when a patient is discharged from his or her current PAC setting to a private home/apartment, board and care home, assisted living, group home, transitional living, or home under the care of an organized home health service organization or hospice.

This measure, adopted under section 1899B(c)(1)(E) of the Act, was developed to be a standardized measure for the IRF QRP, LTCH QRP, SNF QRP and Home Health (HH) QRP. The measure is calculated by one standardized data element that asks, ''At the time of discharge, did the facility provide the patient's current reconciled medication list to the patient, family, and/or caregiver?'' The discharge location is captured by items on the Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS).

Specifically, this rule proposes to update the measure denominator. Currently, the measure denominators for both the TOH-Patient measure and the TOH-Provider measure assess the number of patients discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the SNF QRP, IRF QRP, and HH QRP, and avoid counting the patient in both TOH measures in the LTCH QRP, we are proposing to remove this location from the definition of the denominator for the TOH-Patient measure. Therefore, we are proposing to update the denominator for the TOH-Patient measure to only discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living. For additional technical information regarding the TOH-Patient measure, we refer readers to the document titled ''Final Specifications for LTCH QRP Quality Measures and Standardized Patient Assessment Data Elements (SPADEs)'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Final-Specifications-for-LTCH-QRP-Quality-Measures-and-SPADEs.pdf*.

We invite public comment on our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 LTCH QRP.

5. LTCH QRP Quality Measures Under Consideration for Future Years: Request for Information

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures and concepts under consideration listed in Table FF2 for future years in the LTCH QRP.

Table IX.E.-02: Future Measures and Measure Concepts Under Consideration for the LTCH QRP

Assessment-Based Quality Measures and Measure Concepts
Frailty
Opioid use and frequency
Patient reported outcomes
Shared decision making process
Appropriate pain assessment and pain management processes
Malnutrition
Health equity

While we will not be responding to specific comments submitted in response to this Request for Information in the FY 2022 IPPS/LTCH PPS final rule, we intend to use this input to inform our future measure development efforts.

6. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs—Request for Information (RFI)

a. Background

The LTCH QRP is authorized by section 1886(m)(5) of the Act and furthers our mission to improve the quality of health care for beneficiaries through measurement, transparency, and public reporting of data. The LTCH QRP and CMS's other quality programs are foundational for contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework captures our vision to address health care quality priorities and gaps, including

emphasizing digital quality measurement (dQM), reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework has evolved to accommodate the changes in the health care environment, initially focusing on measure and burden reduction to include the promotion of innovation and modernization of all aspects of quality.[1389] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

In alignment with Meaningful Measures 2.0, we are seeking feedback on our future plans to define digital quality measures (dQMs) for the LTCH QRP. We also are seeking feedback on the potential use of Fast Healthcare Interoperable Resources (FHIR) for dQMs within the LTCH QRP aligning where possible with other quality programs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) establishes a common language and process for all health information technology.

b. Definition of Digital Quality Measures

We are considering proposing to adopt a standardized definition of Digital Quality Measures (dQMs) in alignment across quality programs, including the LTCH QRP. We are considering in the future to propose the adoption within the LTCH QRP the following definition: Digital Quality Measures (dQMs) are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems.[1390] A dQM includes a calculation that processes digital data to produce a measure score or measure scores. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. As an example, the quality measures calculated from patient assessment data submitted electronically to CMS would be considered digital quality measures.

c. Use of FHIR for Future dQMs in the LTCH QRP

One of the first areas CMS has identified relative to improving our digital strategy is through the use of Fast Healthcare Interoperability Resources (FHIR)-based standards to exchange clinical information through application programming interfaces (APIs), aligning with other programs where possible, to allow clinicians to digitally submit quality information one time that can then be used in many ways. We believe that in the future proposing such a standard within the LTCH QRP could potentially enable collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost.

We are currently evaluating the use of FHIR based APIs to access assessment data collected and maintained through the Quality Improvement and Evaluation System (QIES) and internet QIES (iQIES) health information systems and are working with healthcare standards organizations to assure that their evolving standards fully support our assessment instrument content. Further, as more LTCHs are adopting EHRs, we are evaluating using the FHIR interfaces for accessing patient data (including standard assessments) directly from LTCH EHRs. Accessing data in this manner could also enable the exchange of data for purposes beyond data reporting to CMS, such as care coordination further increasing the value of EHR investments across the healthcare continuum. Once providers map their EHR data to a FHIR API in standard FHIR formats it could be possible to send and receive the data needed for measures and other uses from their EHRs through FHIR APIs.

d. Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to achieve interoperable data exchange and to transition to full digital quality measurement in our quality programs. We are considering the future potential development and staged implementation of a cohesive portfolio of dQMs across our quality programs (including the LTCH QRP), agencies, and private payers. This cohesive portfolio would require, where possible, alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measures. Further, the required data elements would be limited to standardized, interoperable elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and State agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and State agencies and payers to the extent possible.

We intend this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, patient reported outcomes (PROs), disparities, care coordination), and track with the transformation of data collection. This includes conformance with standards and health IT module updates, future adoption of technologies incorporated within the ONC Health IT Certification Program and may also include standards adopted by ONC (for example, to enable standards-based APIs). The coordination would build on the principles outlined in *HHS' National Health Quality Roadmap.*[1391] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (DoD/VA); the Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, NQF, provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in

[1389] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[1390] Definition taken from the CMS Quality Conference 2021.

[1391] Department of Health and Human Services. National Health Quality Roadmap. May 15, 2020. Available at: *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, State, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements as well as the requirements of other agencies and payers.

e. Solicitation of Comments

We seek input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital:

i. What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?

ii. How do you currently share information with other providers?

iii. In what ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to LTCHs?

iv. What additional resources or tools would post-acute care settings, including but not limited to LTCHs, and health IT vendors find helpful to support the testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?

v. Would vendors, including those that service post-acute care settings, such as LTCHs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?

We plan to continue working with other agencies and stakeholders to coordinate and to inform our transformation to dQMs leveraging health IT standards. While we will not be responding to specific comments submitted in response to this RFI in the FY 2022 IPPS/LTCH PPS final rule, we will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

7. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information (RFI)

a. Background

Significant and persistent inequities in health outcomes exist in the United States. In recognition of persistent health disparities and the importance of closing the health equity gap, we request information on revising several CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for providers and patients. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; or being near or below the poverty level, is often associated with worse health outcomes.[1392] [1393] [1394] [1395] [1396] [1397] [1398] [1399] Such disparities in health outcomes are the result of a number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and operative complications.[1400] [1401] [1402] [1403] [1404] [1405] Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for Black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[1406] [1407] [1408] [1409] [1410] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[1411] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among Black, Latino, and Indigenous and Native American persons relative to white persons.[1412] [1413] As noted by the Centers for Disease Control ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying

[1392] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[1393] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[1394] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[1395] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[1396] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[1397] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[1398] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[1399] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[1400] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[1401] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[1402] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[1403] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[1404] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[1405] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[1406] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[1407] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[1408] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[1409] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[1410] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[1411] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[1412] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[1413] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

from COVID–19''.[1414] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies.

We are also committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[1415] [1416] For the purposes of this rule, we are using a definition of ''equity'' established in Executive Order 13985 as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [1417] We note that this definition was recently established by the current administration, and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs, including the PAC QRPs, is demonstrated by a portfolio of programs aimed at making information on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Networks and Quality Improvement Organizations (QIN–QIOs); Federal, State, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity. The CMS Equity plan includes three core elements: (1) Increasing understanding and awareness of disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[1418] The CMS Quality Strategy and Meaningful Measures Framework [1419] include elimination of racial and ethnic disparities as a central principle. Our ongoing commitment to closing the health equity gap in the LTCH QRP is demonstrated by the adoption of standardized patient assessment data elements (SPADEs) which include several social determinants of health (SDOH) that were finalized in the FY 2020 IPPS/LTCH PPS final rule for the LTCH QRP (84 FR 42577 through 42588).

We continue to work with public and private partners to better leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection [1420] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health. We continue to work to improve our understanding of this important issue and to identify policy solutions that achieve the goals of attaining health equity for all patients.

b. Solicitation of Public Comment

Under the authority of the IMPACT Act and section 1886(m)(5) of the Act, we are seeking comment on the possibility of revising measure development, and the collection of other SPADEs that address gaps in health equity in the LTCH QRP. Any potential data collection or measure reporting related to health equity within a CMS program, including the LTCH QRP, that might result from public comments received in response to this solicitation would be addressed through a separate notice-and-comment rulemaking in the future.

Specifically, we are inviting public comment on the following:

- Recommendations for quality measures, or measurement domains that address health equity, for use in the LTCH QRP.
- As finalized in the FY 2020 IPPS/LTCH PPS Final Rule (84 FR 42577 through 42588), LTCHs must report certain SPADEs on SDOH, including race, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[1421] CMS is seeking guidance on any additional SPADEs that could be used to assess health equity in the care of LTCH patients, for use in the LTCH QRP.
- Recommendations for how CMS can promote health equity in outcomes among LTCH patients. For example, we are interested in feedback regarding whether including facility-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow facilities to identify gaps in the quality of care they provide. (For example, methods similar or analogous to the CMS Disparity Methods [1422] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures, which are currently included in the Hospital Readmission Reduction Program (see 84 FR 42496 through 42500)).
- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.
- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges LTCHs encounter for effective capture, use, and exchange of health information, including data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

[1414] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[1415] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[1416] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.*

[1417] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government.*

[1418] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[1419] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[1420] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[1421] In response to the COVID–19 PHE, CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least one full fiscal year after the end of the PHE.

[1422] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

While we will not be responding to specific comments submitted in response to this RFI in the FY 2022 IPPS/LTCH PPS final rule, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and note for readers that responses to the RFI should focus on how they could be applied to the quality reporting program requirements. Please note that any responses provided will not impact payment decisions.

8. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulatory text at 42 CFR 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

b. Proposed Schedule for Data Submission of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure Beginning With the FY 2023 LTCH QRP

As discussed in section E.4.a. of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2023 LTCH QRP. Given the time-sensitive nature of this measure in light of the PHE, we propose an initial data submission period from October 1, 2021 through December 31, 2021. Starting in CY 2022, LTCHs would be required to submit data for the entire calendar year beginning with the FY 2024 LTCH QRP.

LTCHs would submit data for the measure through the CDC/NHSN web-based surveillance system. LTCHs currently utilize the NHSN for purposes of meeting other LTCH QRP requirements.[1423] LTCHs would use the COVID–19 vaccination data collection module in the NHSN Healthcare Personnel Safety (HPS) Component to report the cumulative number of HCP eligible to work in the LTCH for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination (denominator) and the cumulative number of HCP eligible to work in the LTCH for at least 1 day during the reporting period and who have received a complete vaccination course against COVID–19 (numerator). LTCHs would submit COVID–19 vaccination data through the NHSN for at least one week each month and the CDC would report to CMS quarterly.

We invite public comment on this proposal.

9. Proposed Policies Regarding Public Display of Measure Data for the LTCH QRP

a. Background

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public, including the performance of individual LTCHs, after ensuring that LTCHs have the opportunity to review their data prior to public display. LTCH QRP measure data are currently displayed on the *Long-term care hospitals* website within Care Compare and the Provider Data Catalog, which are CMS websites. Both Care Compare and the Provider Data Catalog replaced LTCH Compare and *Data.Medicare.gov,* which were retired in December 2020. For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236).

b. Proposal To Publicly Report the Compliance With Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay Measure Beginning With the FY 2023 LTCH QRP

We propose public reporting for the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure beginning with the March 2022 Care Compare refresh or as soon as technically feasible using four rolling quarters of discharge data collected in Q3 2020 through Q2 2021 (July 1, 2020 through June 30, 2021) for the inaugural display of this measure. We propose publicly reporting the Compliance with SBT by Day 2 of the LTCH Stay measure for data collected from July 1, 2018 through December 31, 2019 on CMS' Provider Data Catalog (PDC) web page. We adopted the Compliance with SBT by Day 2 of the LTCH Stay measure in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38439 through 38446). Data collection for this assessment-based measure began with patients admitted and discharged on or after July 1, 2018. To ensure the statistical reliability of the data, we propose not to publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases [1424] during each performance period. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

LTCHs were required to collect and submit data for the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure beginning on July 1, 2018 (Q3 2018), six calendar year quarters prior to the data proposed for the inaugural display of the measure on Care Compare. The first quarter of data collected and submitted by LTCHs (that is, Q3 2018) will be nearly 3.5 years old at that time. Therefore, CMS believes it is in the best interest of providers and the public to use the most recent available four quarters of data (that is July 1, 2020 through June 30, 2021) for the inaugural public display of the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure on Care Compare and to post provider performance on the Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure using the older data (that is, July 1, 2018 through December 31, 2019) on CMS' Provider Data Catalog (PDC) web page (*https://data.cms.gov/provider-data/*).

We invite public comment on the proposal to publicly display the measure, Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay measure on Care Compare and PDC.

c. Proposal To Publicly Report the Ventilator Liberation Rate for the PAC LTCH QRP Measure Beginning With the FY 2023 LTCH QRP

We propose public reporting for the Ventilator Liberation Rate for the PAC LTCH QRP measure, beginning with the March 2022 Care Compare refresh or as soon as technically feasible using four rolling quarters of discharge data collected in Q3 2020 through Q2 2021 (July 1, 2020 through June 30, 2021) for the inaugural display of this measure. We propose publicly reporting the Ventilator Liberation rate for the PAC LTCH QRP measure for data collected from July 1, 2018 through December 31, 2019 on CMS' Provider Data Catalog (PDC) web page. We adopted the Ventilator Liberation Rate measure in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38439 through 38446). Data collection for this assessment-based

[1423] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at: *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

[1424] We define an ''eligible case'' as a case that meets all of the criteria under the measure's denominator, which can be found In the LTCH QRP Measure Calculations and Reporting Manual found on the LTCH QRP Measures Information web page here: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.*

measure began with patients admitted and discharged on or after July 1, 2018. To ensure the statistical reliability of the data, we propose not to publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases during each performance period. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

LTCHs were required to collect and submit data for the Ventilator Liberation Rate for the PAC LTCH QRP measure beginning on July 1, 2018 (Q3 2018), six calendar year quarters prior to the data proposed for the inaugural display of the measure on Care Compare. The first quarter of data collected and submitted by LTCHs (that is, Q3 2018) will be nearly 3.5 years old at that time. Therefore, CMS believes it is in the best interest of providers and the public to use the most recent available four quarters of data (that is July 1, 2020 through June 30, 2021) for the inaugural public display of the Ventilator Liberation Rate for the PAC LTCH QRP measure on Care Compare and to post provider performance on the Ventilator Liberation Rate for the PAC LTCH QRP measure using the older data (that is, July 1, 2018 through December 31, 2019) on CMS' Provider Data Catalog (PDC) web page (*https://data.cms.gov/provider-data/*).

We invite public comment on the proposal to publicly display the measure, Ventilator Liberation Rate for the PAC LTCH QRP on Care Compare and PDC.

d. Proposal To Publicly Report the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 LTCH QRP

We propose to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the September 2022 Care Compare refresh or as soon as technically feasible using data collected for Quarter 4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, a LTCH's HCP COVID–19 vaccination coverage rate would be displayed based on one quarter of data. Provider preview reports would be distributed in June 2022. Subsequent to the September 2022 Care Compare refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four quarters of data is reached. Thereafter, the measure would be publicly reported using four rolling quarters of data.

We invite public comment on this proposal for the public display of the measure, COVID–19 Vaccination Coverage among HCP on Care Compare.

e. Proposals for Public Reporting of Quality Measures in the LTCH QRP With Fewer Quarters Due to COVID–19 Public Health Emergency (PHE) Exemption

(1) COVID–19 Public Health Emergency Temporary Exemptions

Under the authority of section 319 of the Public Health Service Act, the Secretary of Health and Human Services declared a public health emergency (PHE) effective as of January 27, 2020. On March 13, 2020, subsequent to a presidential declaration of national emergency under the Stafford Act, the Secretary invoked Section 1135(b) of the Act (42 U.S.C. 1320b–5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations related to the PHE for COVID–19 effective as of March 1, 2020.[1425] On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[1426] hereafter referred to as the March 27, 2020 CMS Guidance Memo. In that memo we granted an exception to the LTCH–QRP reporting requirements from Q4 2019 (October 1, 2019–December 31, 2019) Q1 2020 (January 1, 2020–March 31, 2020) and Q2 2020 (April 1, 2020–June 30, 2020). We also stated that we would not publicly report any LTCH QRP data that might be greatly impacted by the exceptions from Q1 and Q2 of 2020. This exception impacted the schedule for public reporting that would have included those two quarters of data.

LTCH QRP measures are publicly reported on Care Compare. Care Compare uses four quarters of data for LCDS assessment-based measures, with the exception of the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) which uses eight quarters of data. Care Compare uses eight quarters of data for claims based measures. Table IX.E.-03 displays the original schedule for public reporting of LTCH QRP measures.[1427]

[1425] *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx*

[1426] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[1427] More information about the LTCH QRP Public Reporting schedule can be found on the LTCH QRP Public Reporting website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Public-Reporting.*

Table IX.E.-03. LTCH QRP Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions - Assessment and Claims Based Measures

Quarter Refresh	LTCH QRP Quarters in Original Schedule for Care Compare
Actual December 2020 (on Care Compare)	LCDS: Q1 2019 – Q4 2019 (4 quarters)* LCDS Mobility Measure: Q1 2018 – Q4 2019 (8 quarters)* Claims: Q4 2017 – Q3 2019 (8 quarters)
Original December 2020	LCDS: Q2 2019 – Q1 2020 (4 quarters) LCDS Mobility Measure: Q2 2018 – Q1 2020 (8 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
March 2021	LCDS: Q3 2019 – Q2 2020 (4 quarters) LCDS Mobility Measure: Q3 2018 – Q2 2020 (8 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
June 2021	LCDS: Q4 2019 – Q3 2020 (4 quarters) LCDS Mobility Measure: Q4 2018 – Q3 2020 (8 quarters) Claims: Q4 2017 – Q3 2019 (8 quarters)
September 2021	LCDS: Q1 2020 – Q4 2020 (4 quarters) LCDS Mobility Measure: Q1 2019 – Q4 2020 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
December 2021	LCDS: Q2 2020 – Q1 2021 (4 quarters) LCDS Mobility Measure: Q2 2019 – Q1 2021 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
March 2022	LCDS: Q3 2020 – Q2 2021 (4 quarters) LCDS Mobility Measure: Q3 2019 – Q2 2021 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
June 2022	LCDS: Q4 2020 – Q3 2021 (4 quarters) LCDS Mobility Measure: Q4 2019 – Q3 2021 (8 quarters) Claims: Q4 2018 – Q3 2020 (8 quarters)
September 2022	LCDS: Q1 2021 – Q4 2021 (4 quarters) LCDS Mobility Measure: Q1 2020 – Q4 2021 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)

Quarter Refresh	LTCH QRP Quarters in Original Schedule for Care Compare
December 2022	LCDS: Q2 2021 – Q1 2022 (4 quarters) LCDS Mobility Measure: Q2 2020 – Q1 2022 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
March 2023	LCDS: Q3 2021 – Q2 2022 (4 quarters) LCDS Mobility Measure: Q3 2020 – Q2 2022 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)
June 2023	LCDS: Q4 2021 – Q3 2022 (4 quarters) LCDS Mobility Measure: Q4 2020 – Q3 2022 (8 quarters) Claims: Q4 2019 – Q3 2021 (8 quarters)

*The September 2020 refresh was postponed to December 2020 for technical reasons. The period of performance listed here reflects the data that was originally scheduled to be used to calculate provider performance for the December 2020 refresh.

During 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes which include partially and/or fully exempt data (discussed below). The testing helped us develop a plan for posting data that are as up-to-date as possible and that also meet acceptable standards for public reporting. We believe that the plan allows us to provide consumers with helpful information on the quality of LTCH care, while also making the necessary adjustments to accommodate the exemption provided LTCHs. The following sections provide the results of our testing, and explains how we used the results to develop plans for accommodating exempt and partially-exempt data in public reporting.

(2) Exempted Quarters

In the March 27, 2020 Medicare Learning Network (MLN) Newsletter on Exceptions and Extensions for Quality Reporting Program (QRP) Requirements, we stated that we would not report any PAC quality data that might be greatly impacted by the exemptions granted for Quarter 1 and Quarter 2 of 2020. Given the timing of the PHE onset, we determined that we would not use LCDS assessments or LTCH claims from Quarter 1 and Quarter 2 of 2020 for public reporting, but that we would assess the COVID–19 PHE impact on data from Quarter 4 2019. Before proceeding with the December 2020 refresh, we conducted testing to ensure that, despite the voluntary nature of reporting for that quarter, public reporting would still meet our public reporting standards. We found the level of reporting, measured in the number of eligible stays and providers, and the reported outcomes, to be in line with levels and trends observed in FY 2018 and FY 2019. We note that Quarter 4 2019 ended before the onset of the COVID–19 pandemic in the United States. Thus, we proceeded with including these data in LTCH QRP measure calculations for the December 2020 refresh.

(3) Update on Data Freeze and Proposal for December 2021 Public Reporting Methodology for LTCH Claims-Based and LCDS Assessment-Based Measures

In addition to the March 2021 refresh, there are several other forthcoming refreshes for which the original public reporting schedules included exempted quarters of LTCH QRP data. The impacted refreshes for LCDS assessment and claims based measures are outlined in Table FF3. We determined that freezing the data displayed on the website with the December 2020 refresh values—that is, hold the data constant after the December 2020 refresh data on the website without subsequent update—would be the most straightforward, efficient, and equitable approach for LTCHs. Thus, we decided that, for as many refreshes as necessary, we would hold data constant on the website with the December 2020 data, and communicate this decision to the public.

Because December 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display December 2020 data. Using fewer quarters of more up-to-date data requires that (1) a sufficient percentage of LTCHs would still likely have enough assessment data to report quality measures (reportability); and (2) fewer quarters would likely produce similar measure scores for providers, with similar reliability, and thus not unfairly represent the quality of care LTCHs provide during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting assessment-based measures and using 6 quarters instead of 8 for the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) measure; and using 6 quarters instead of 8 for claims-based measures. Specifically, we used historical data to calculate LCDS assessment based and LTCH claims based measures under two scenarios:

1. *Standard Public Reporting (SPR) Base Scenario:* We used four quarters of CY 2019 data as a proxy alternative for the exempted quarters in CY 2020 in order to compare results. For assessment-based measures, the quarters used in this scenario are Q1 through Q4 2019. For the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) measure, the quarters used in this scenario are Q1 2018 through Q4 2019. For claims-based measures, the quarters used in this scenario are Q1 2018 through Q4 2019.

2. *COVID–19 Affected Reporting (CAR) Scenario:* We calculated LTCH QRP measures using 3 quarters (Q2 2019 through Q4 2019) of LTCH QRP data for assessment-based measures, 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients requiring Ventilator Support (NQF #2632) measure, and 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for claims-based measures. The CAR scenario uses the most recently available data to simulate the public health emergency reality where quarters 1 and 2 of a calendar year must be excluded from calculation. Quarterly trends in LCDS assessment-based and LTCH claims-based measures indicate that these measures do not exhibit substantial seasonal variation.

To assess performance in these scenarios, we calculated the reportability as the percent of LTCHs meeting the case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the LTCHs included in the SPR Base Scenario to those included in the CAR Scenario, we performed three tests on the set of LTCHs included in both scenarios. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of LTCHs' provider scores. Second, for each scenario, we conducted a split-half reliability analysis and estimated intraclass correlation (ICC) scores, where higher scores imply better internal reliability. Modest differences in ICC scores between scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores where a higher value indicates that measure scores are relatively consistent for patients admitted to the same LTCH and variation in the measure reflects true differences across providers. To calculate the reliability results, we restricted the LTCHs included in the SPR scenario to those included in the CAR scenario. Our testing indicated that the expected impact of using fewer quarters of data on reportability and reliability of LCDS assessment-based and claims-based measures is acceptable.

We are proposing to use the CAR scenario as the approach for the following affected refreshes: For LCDS assessment-based measures, the affected refresh is the December 2021 refresh; for claims-based measures, the affected refreshes occur from December 2021 through June 2023. For the earlier three affected refreshes (March, June and September 2021), we decided to hold constant the Care Compare website with December 2020 data. We communicated this decision in a Public Reporting Tip Sheet, which is located at: *https://www.cms.gov/files/document/LTCHqrp-covid19prtipsheet-october-2020.pdf*.

Our proposal of the CAR approach for the affected refreshes would allow us to begin displaying more recent data in December 2021, rather than continue displaying December 2020 data (Q1 2019 through Q4 2019 and Q1 2018 through Q4 2019 for assessment-based measures, Q4 2017 through Q3 2019 for claims-based measures). We believe resuming public reporting starting in December 2021 with fewer quarters of data can assist consumers by providing more recent quality data as well as more actionable data for LTCH providers. Our testing results indicate we can achieve these positive impacts with acceptable changes in reportability and reliability. Table IX.E.-04 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for assessment-based measures. Table IX.E.-05 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for claims-based measures.

We invite public comments on the proposal to use the CAR scenario to publicly report LTCH measures for the December 2021–June 2023 refreshes.

Table IX.E.-04. Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for LCDS Assessment-based QMs

Quarter Refresh	LCDS Assessment based Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)^
December 2020	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
March 2021	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
June 2021	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
September 2021	Q1 2019 – Q4 2019 (4) Q1 2018 – Q4 2019 (8)
December 2021	Q3 2020 – Q1 2021 (3) Q2 2019 – Q42019, Q3 2020 – Q1 2021 (6)
March 2022*	Q3 2020 – Q2 2021 (4)

Quarter Refresh	**LCDS Assessment based Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)^**
	Q3 2019 – Q42019, Q3 2020 – Q2 2021 (6)
June 2022	Q4 2020 – Q3 2021 (4) Q42019, Q3 2020 – Q3 2021 (6)
September 2022	Q1 2021 – Q4 2021 (4) Q4 2019, Q3 2020 – Q4 2021 (7)
December 2022	Q2 2021 – Q1 2022 (4) Q4 2019, Q3 2020 – Q1 2022 (8)
March 2023**	Q3 2021 – Q2 2022 (4) Q3 2020 – Q2 2022 (8)

Note: The shaded cells represent data held constant due to PHE related to COVID-19.
^The Change in Mobility Among LTCH Patients Requiring Ventilator Support requires 8 quarters of data whereas the remaining LCDS measures require 4 quarters.
*Normal reporting resumes with 4 quarters of data for most LCDS measures.
** All LCDS measures will normalize in the March 2023 refresh.

Table IX.E.-05. Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for LTCH Claims-based QMs

Quarter Refresh	Claims-based Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q3 2019 (8)
March 2021	Q4 2017 – Q3 2019 (8)
June 2021	Q4 2017 – Q3 2019 (8)
September 2021	Q4 2017 – Q3 2019 (8)
December 2021	Q4 2018 – Q4 2019, Q3 2020 (6)
March 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
June 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
September 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
December 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
March 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
June 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
September 2023	Q4 2020 – Q3 2022 (8)* *Normal reporting resumes with 8 quarters of data

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

(4) Update on Data Freeze and Proposal for December 2021 Public Reporting Methodology for NHSN-Based Measures

CDC recommends using the four most recent non-contiguous non-exempted quarters of data for NHSN reporting in the LTCH QRP. This non-contiguous compilation of quarterly reporting would continue until the time when four contiguous quarters of reporting resumes (based on CDC's review, this would occur in July 2022). Tables IX.E.-06 and 07 display the original schedules for public reporting of LTCH CDI, CAUTI and CLABSI measures and the HCP Influenza measure, respectively. Tables IX.E.-08 and 09 summarize the revised schedule and the proposed schedule for LTCH CDI, CAUTI, and CLABSI measures and the HCP Influenza measure, respectively.

Table IX.E.-06. LTCH QRP Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions CDI, CAUTI, and CLABSI NHSN Measures

Quarter Refresh	CDI, CAUTI, and CLABSI Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2018 – Q3 2019 (4)*
Original December 2020	Q1 2019 – Q4 2019 (4)
March 2021	Q2 2019 – Q1 2020 (4)
June 2021	Q3 2019 – Q2 2020 (4)
September 2021	Q4 2019 – Q3 2020 (4)
December 2021	Q1 2020 – Q4 2020 (4)
March 2022	Q2 2020 – Q1 2021 (4)
June 2022	Q3 2020 – Q2 2021 (4)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

Table IX.E.-07. LTCH QRP Quarters in Care Compare Original Schedule for Refreshes Affected by COVID-19 PHE Exemptions - HCP Influenza Measure

Quarter Refresh	HCP Influenza Quarters in Original Schedule for Care Compare (number of quarters)
Actual December 2020 (on Care Compare)	Q4 2017 – Q1 2018 (2)*
December 2020	Q4 2018 – Q1 2019 (2)
March 2021	Q4 2018 – Q1 2019 (2)
June 2021	Q4 2018 – Q1 2019 (2)
September 2021	Q4 2018 – Q1 2019 (2)
December 2021	Q4 2019 – Q1 2020 (2)
March 2022	Q4 2019 – Q1 2020 (2)
June 2022	Q4 2019 – Q1 2020 (2)
September 2022	Q4 2019 – Q1 2020 (2)
December 2022	Q4 2020 – Q1 2021 (2)

*The September 2020 refresh was postponed to December 2020 for technical reasons.

Table IX.E-08. Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the CDI, CAUTI, and CLABSI NHSN Measures

Quarter Refresh	CDI, CAUTI, and CLABSI Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2018 – Q3 2019 (4)
March 2021	Q4 2018 – Q3 2019 (4)
June 2021	Q4 2018 – Q3 2019 (4)
September 2021	Q4 2018 – Q3 2019 (4)
December 2021	Q1 2019 – Q4 2019 (4)
March 2022	Q2 2019 – Q4 2019, Q3 2020 (4)
June 2022*	Q3 2020 – Q2 2021 * Normal reporting resumes with 4 contiguous quarters of data.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

Table IX.E.-09. Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the HCP Influenza NHSN Measure

Quarter Refresh	HCP Influenza Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
December 2020	Q4 2017 – Q1 2018 (2)
March 2021	Q4 2017 – Q1 2018 (2)
June 2021	Q4 2017 – Q1 2018 (2)
September 2021	Q4 2017 – Q1 2018 (2)
December 2021	Q4 2018 – Q1 2019 (2)
March 2022	Q4 2018 – Q1 2019 (2)
June 2022	Q4 2018 – Q1 2019 (2)
September 2022	Q4 2018 – Q1 2019 (2)
December 2022	Q4 2020 – Q1 2021 (2)* * Normal reporting resumes.

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

F. Proposed Changes to the Medicare Promoting Interoperability Program

1. Background

a. Statutory Authority for the Medicare Promoting Interoperability Program

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorized incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which included reporting on clinical quality measures using CEHRT. Incentive payments were available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that successfully demonstrated meaningful use of CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare generally are no longer available, except for Puerto Rico eligible hospitals. For more information on the Medicare incentive payments available to Puerto Rico eligible hospitals, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58976 and 58977) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41672 through 41675).

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also established downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that did not successfully demonstrate meaningful use of CEHRT for certain associated electronic health record (EHR) reporting periods. Section 1853(m)(4) of the Act established a negative payment adjustment to the monthly prospective payments for a qualifying MA organization if its affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015.

Section 1903(a)(3)(F)(i) of the Act established 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT. We previously established, however, that in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after CY 2021 (42 CFR 495.310(f), 75 FR 44319). Therefore, December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to CY 2021 or a prior year) (84 FR 42591 through 42592). For additional discussion or context around the discontinuation of the Medicaid Promoting Interoperability Program, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41676 through 41677).

2. EHR Reporting Period

a. Background

Under the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, the EHR reporting period in CY 2022 is a minimum of any continuous 90-day period in CY 2022 for new and returning participants in the Medicare Promoting Interoperability Program. Eligible hospitals and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period in CY 2022 (from January 1, 2022 through December 31, 2022) (85 FR 58966 through 58967). Since the EHR reporting period in CY 2015 (see 80 FR 62777 through 62781, and the definitions of EHR reporting period and EHR reporting period for a payment adjustment year at 495.4), we have consistently established an EHR reporting period of any continuous 90-day period for eligible hospitals and CAHs for the Medicare Promoting Interoperability Program in order to provide maximum flexibility to providers and their health IT vendors.

b. Proposed EHR Reporting Period in CY 2023 and CY 2024 for Eligible Hospitals and CAHs

For CY 2023, we are proposing to continue the EHR reporting period of a minimum of any continuous 90-day period for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program.

For CY 2024, we are proposing an EHR reporting period of a minimum of

any continuous 180-day period for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program.

We are proposing to amend the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4 to include these proposed EHR reporting periods in CYs 2023 and 2024.

This CY 2024 proposal would minimally increase the information collection burden on data submitters, and having additional data available to further improve our program is beneficial. In increasing the EHR reporting period in CY 2024, this would allow eligible hospitals, CAHs, and vendors time to plan in advance, build upon, and utilize investments already made within their infrastructure. Reporting on additional data would also provide eligible hospitals and CAHs the opportunity to continuously monitor their performance and identify areas that may require investigation and corrective action. Increasing the EHR reporting period in CY 2024 is important for the continued improvement of interoperability and health information exchange by producing more comprehensive and reliable data for patients and providers, which are key goals of the Medicare Promoting Interoperability Program.

We are seeking comment on the proposed EHR reporting periods in CYs 2023 and 2024, and proposed changes to the regulation text at 42 CFR 495.4.

3. Proposed Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

a. Measure Background

We have adopted a Query of Prescription Drug Monitoring Program (PDMP) measure under the Electronic Prescribing objective. For background on this measure, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41656), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969). In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), we finalized that the Query of PDMP measure will remain optional and eligible for 5 bonus points in CY 2021.

b. State PDMPs' Progress and Previous Stakeholder Feedback

In the FY 2020 and FY 2021 IPPS/LTCH PPS final rules (84 FR 42593 through 42596 and 85 FR 58967 through 58969), we described the concern expressed by stakeholders that they believed it was premature for the Medicare Promoting Interoperability Program to require the Query of PDMP measure and score it based on performance. Feedback received from health IT vendors and hospitals expressed that flexibility in the measure presents unintended challenges such as significant burden associated with IT system design and additional development needed to accommodate the measure and any future changes to it.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to specify a single approach to PDMP–EHR integration at this time. At the same time, we have heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications. These stakeholders stated that health IT developers may face significant cost burdens if they fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Stakeholders have noted that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure (for public comments discussed in last year's final rule, we refer readers to 85 FR 58967 through 58969).

In support of efforts to expand the use of PDMPs, there are currently a number of federally supported activities underway aimed at developing a more robust and standardized approach to EHR–PDMP integration. Federal partners, including the CDC and ONC, and private sector stakeholders, are focused on developing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck, which is a federally supported interstate exchange hub for PDMP data.[1428] The ONC Interoperability Standards Advisory describes current and emerging standards related to PDMP and opioid use disorder (OUD) data capture and exchange that would allow a provider to request a patient's medication history from a State PMDP and for PDMP data to be exchanged between systems and states.[1429] We believe these standards and technical approaches are likely to rapidly reach maturity to support exchange across health care system stakeholders.

The SUPPORT for Patients and Communities Act (Pub. L. 115–271), enacted in 2018, is an important investment in combating the opioid epidemic. Several of the provisions of the SUPPORT for Patients and Communities Act address opioid use disorder prevention, recovery, and treatment, including legislative changes specific to the Medicare and Medicaid programs intended to increase access to evidence-based treatment and follow-up care. However, with respect to PDMPs, the SUPPORT for Patients and Communities Act included new requirements and Federal funding for PDMP enhancement, integration, and interoperability, and established mandatory use of PDMPs by certain Medicaid providers to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorder beginning in October of 2021.

c. Proposed Measure Changes

Given current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns about the current readiness across states for implementation of the existing measure, we believe that at least one more year is needed prior to potentially requiring the Query of PDMP measure.

While we appreciate the concerns that stakeholders have shared, we continue to believe that this measure can play an important role in helping to address the opioid crisis. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders,

[1428] *https://www.pdmpassist.org/RxCheck.*

[1429] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

inform the development of care plans, and develop effective interventions. Maintaining it as an optional measure with bonus points signals to the hospital and vendor community that this is an important measure which addresses a current gap that can help spur development and innovation in order to reduce barriers and challenges.

Therefore, we are proposing for the EHR reporting period in CY 2022 to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its associated bonus points from 5 points to 10 points, as well as proposing corresponding changes to the regulation at 495.24(e)(5)(iii)(B). As a result of this proposal, the maximum total points available for the Electronic Prescribing Objective would increase to 20 points for CY 2022, and we are proposing to revise 495.24(e)(5)(ii)(B) to reflect this increase. This proposed increase of the measure's associated bonus points to 10 points is consistent with the policy finalized for MIPS eligible clinicians in the CY 2021 PFS final rule (85 FR 84887 through 84888) and would be in alignment with the MIPS Promoting Interoperability performance category.

We seek comments on our proposal to maintain the Query of PDMP measure in the EHR reporting period in CY 2022 as optional and to increase the bonus points associated with the measure to 10 bonus points.

d. Health IT Updates and Measure Direction

Given recent progress in a variety of areas, we believe that there is now a clearer trajectory forward to potentially requiring the Query of PDMP measure. These developments include updated requirements for certified health IT, standards development activities around PDMPs, and other projects that can more tangibly inform future policy changes. For example, under final policies recently adopted in the CY 2021 Physician Fee Schedule final rule (85 FR 84815 through 84828), participants in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category will begin using certified EHR technology incorporating APIs based on HL7® FHIR® standard version Release 4 in CY 2023 consistent with updates to certified health IT which were finalized in the ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (hereinafter referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961 and 25740).[1430] Updates to 2015 Edition health IT certification criteria in the ONC 21st Century Cures Act final rule also incorporated NCPDP SCRIPT standard version 2017071 for electronic prescribing. The availability of both standardized APIs and updated standards for e-prescribing within certified health IT could serve as a stepping stone to future technical approaches that enable more seamless exchange of data between CEHRT and PDMP systems.

A number of recent efforts have sought to improve interoperability between EHRs and PDMPs. In 2020, ONC completed work to map the NCPDP SCRIPT standard version 2017071, the Prescription Monitoring Information eXchange (PMIX) standard version 2, and the 2015 American Society for Automation in Pharmacy (ASAP) Prescription Monitoring Program Web Service standard version 2.1A to the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard version Release 4.

ONC also began work in partnership with the CDC, the Department of Justice's Bureau of Justice Assistance, and the eHealth Exchange to develop a prototype to pilot an innovative technical solution for the delivery of patient medication histories across State lines via HL7® FHIR®. The eHealth Exchange is a network of networks that is active in all 50 states connecting Federal and non-Federal healthcare organizations to improve patient care and public health. To date, the prototype has been successfully tested in several states. Early prototype testing used synthetic data to evaluate system capacity to send and receive a patient's medication history request and response. The goal of the project is to allow any provider who is live on the eHealth Exchange to use that existing connection to query a patient's record on the RxCheck Hub, which routes the query to individual State PDMPs who are also live on RxCheck. This solution will enable providers to query PDMPs via existing connections to health information exchange networks as a way to: (1) Leverage existing technology, (2) reduce burden associated with multiple, disparate system interfaces and workflows, and (3) allow for the exchange and full integration of data within allowable law from the point of exchange for medication reconciliation, allergy checks, and other forms of clinical decision support.

Based upon these developments, which are advancing enhanced certified functionality, effective functional data exchange, and the use of open, mature standards, we believe there is a much better informed roadmap for achieving better integration between PDMPs and EHRs with enhanced interoperability of controlled prescription data across states and systems. We believe that as these activities develop, they can help to address some of the previous concerns raised by stakeholders around this measure, and we will continue to work with ONC to monitor these activities.

While we believe the Query of PDMP measure is very important to avoid and address the over-prescribing of opioids, we also recognize that some states and systems may not be ready at this time to effectively exchange this data. In light of further work in this area and our stated goals for increasing the impact of this measure, we are seeking stakeholder comment on plans for requiring the Query of PDMP measure in the Medicare Promoting Interoperability Program in the near future. To advance in this direction with both transparent proposals and informed guidance, we request public comment on the future direction for the measure, specifically:

- To what degree would all eligible hospitals and CAHs be prepared to report on the current attestation-based Query of PDMP measure in the near future? What additional considerations would need to be addressed before transitioning to a performance-based version of the measure?
- Would changes to the Query of PDMP measure be necessary to accommodate other technical approaches that may be implemented in the future, such as exchange of information with a PDMP or with multiple PDMPs using HL7® FHIR®?
- What, if any, exclusions should be made available as part of the measure's specifications with regard to eligible hospitals and CAHs?
- When will State PDMPs be ready to effectively exchange data with provider systems using HL7® FHIR® to support this measure? What are the most common standards and approaches used to access PDMP data through provider systems currently?
- What technical considerations exist for intrastate vs. interstate PDMP queries? How could health information exchange networks play a role in expanding access to PDMP data? In what ways could FHIR® applications be supported to safely share PDMP data within a clinician's workflow?

[1430] HL7® and FHIR® are registered trademarks of Health Level Seven International.

4. Proposed Changes to the Provide Patients Electronic Access to Their Health Information Measure Under the Provider to Patient Exchange Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41668), we renamed the Patient Electronic Access Objective to the Provider to Patient Exchange Objective. This objective includes the Provide Patients Electronic Access to Their Health Information measure.

b. Proposed Data Availability Requirement for Eligible Hospitals and CAHs

We are proposing to modify the Provide Patients Electronic Access to Their Health Information measure to require eligible hospitals and CAHs to ensure that patient health information remains available to the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAH's CEHRT, as described under 495.24(e)(7)(ii)(B). Eligible hospitals and CAHs would be required to ensure this information remains available indefinitely (that is, not merely for a defined period of time). The proposed requirement would apply beginning with the EHR reporting period in CY 2022, and would include all patient health information from encounters on or after January 1, 2016. We are proposing to add corresponding regulatory text at 495.24(e)(7)(ii)(C), as well as proposing to restructure some of the existing text under 495.24(e)(7) to improve clarity and readability.

In the Patient Access and Interoperability final rule (85 FR 25510, 25527 through 25528), we finalized that beginning on January 1, 2021, MA organizations, Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers on the FFEs must make available to beneficiaries and enrollees through a Patient Access API, certain claims and clinical data that they maintain with a date of service on or after January 1, 2016. Recognizing the challenges faced by payers during the COVID–19, we announced we it will exercise enforcement discretion and not enforce these new requirements until July 1, 2021.[1431] The look-back period finalized in the Patient Access and Interoperability final rule aimed to align with the required policy for payer-to-payer data exchange finalized in the same rule, providing patients with the same timeframe of information as payers to ensure consistent implementation, while minimizing cost and burden and maximizing patient benefit (85 FR 25542). The finalized look-back period for payers also required that data be available for 5 years after disenrollment (§ 422.119(f)).

Currently, the Provide Patients Electronic Access to Their Health Information measure does not specify how long eligible hospitals and CAHs are required to make patient data available or ensure that patient data remain available to patients in the event that an eligible hospital or CAH switches EHR vendors. In an effort to minimize stakeholder burden, we want to align the date under our proposal for making information about encounters available, with the date of service start date (January 1, 2016) finalized in the Patient Access and Interoperability final rule. As an alternative to our proposal, we considered different encounter start dates, such as encounters on or after January 1, 2012, or encounters on or after January 1, 2019. We believe, however, that a requirement for hospitals to ensure patient health information remains available indefinitely, as well as an encounter start date of January 1, 2016 would provide the most benefit to patients when accessing their health information as compared to the burden and costs to eligible hospitals and CAHs implementing these proposed requirements.

We are seeking public comment on our proposal to modify the Provide Patients Electronic Access to Their Health Information measure, as well as the alternatives we considered.

5. Health Information Exchange Objective: Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

a. Background

Organizations that provide health information exchange services (HIEs) allow for the sharing of health information among clinicians, hospitals, care coordinators, labs, radiology centers, and other health care providers through secure, electronic means so that health care providers can have the benefit of the most recent information available from other health care providers. HIEs allow for broader interoperability beyond one health system or point-to-point connections among payers, patients, and health care providers. By enabling bi-directional exchange of information between health care providers and aggregating data across providers with disparate systems, HIEs can bring together the information needed to create a true longitudinal care record and support improved care coordination by facilitating timely access to robust health information across care settings. For the purposes of this proposal, bi-directional exchange means that the hospital's EHR enables querying and sharing data by sending, receiving, and incorporating data via an HIE for all unique patients treated in place of service inpatient hospital or emergency department (POS 21 and 23 respectively). Healthcare quality and public health outcomes have been shown in multiple studies to experience a beneficial effect from health information exchanges with improved medication reconciliation, improved immunization and health record completeness, and improved population level immunization rates,[1432] while other research has shown a decrease in emergency department utilization and improved care process when using an HIE.[1433]

HIE services are available from many organizations today, which may be referred to as HIEs, health information networks, health information organizations (HIOs), or other terms. State and regional HIEs have a long history of connecting health care providers caring for a common patient population across a specified geographic area. These HIEs represent a significant public investment, with $564 million in Federal funding provided as part of the 2009 HITECH Act, ongoing State funding and support from CMS under both 42 CFR 495.322 and 42 CFR 433 Subpart C.[1434] These State and regional HIEs typically obtain not just EHR-generated data, but a broader array of ADT (admit, discharge, transfer) feeds and lab feeds as they build on local relationships. These HIEs may have similar but not identical capabilities, employing different models of data storage and a variety of business models. Regional and State-based exchanges have also begun to address national-level exchange, with efforts designed to link State and regional

[1431] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.*

[1432] *https://academic.oup.com/jamia/article/25/9/1259/4990601*: *ibid.*

[1433] *https://pubmed.ncbi.nlm.nih.gov/27521368/*: Journal of the American Medical Informatics Association. 2017 Apr 1;24(e1):e103-e110. doi: 10.1093/jamia/ocw116. "*Health Information Exchange Associated With Improved Emergency Department Care Through Faster Accessing of Patient Information From Outside Organizations*".

[1434] *https://protect2.fireeye.com/url?k=d8978709-84c28e1a-d897b636-0cc47adb5650-e634c1ba410d0153&u=https://www.healthit.gov/sites/default/files/reports/finalsummativereportmarch_2016.pdf.*

networks so that health care providers can obtain information on individual patients wherever they receive care throughout the United States. In addition to these initiatives, many EHR vendors are participating in the development of national-level networks designed to ensure their customers can share information with customers of other vendors.

Recent data indicate that there is wide availability of HIEs across the nation, yet gaps remain. Forthcoming analysis of a recent survey of HIEs found that 45 states, including DC, were covered by one or more operational HIOs that reported a statewide catchment area. Moreover, 81 percent (or 2,770) of health service areas (HSAs) in the United States were in the catchment area of at least one operational HIE effort and 32 percent of HSAs had more than one operational HIE effort.[1435] Despite the widespread availability of HIE services, however, HIE participation data suggest there are still significant opportunities to increase health care provider engagement with HIEs. For instance, in a 2019 survey, 74 percent of hospitals reported participating in either a State, regional, or local HIE and 69 percent reported participation in a national HIE network, 11 percent of hospitals reported not participating in any type of HIE.[1436]

b. Proposed New Health Information Exchange (HIE) Bi-Directional Exchange Measure

We believe that incentivizing participation in HIEs that support bi-directional exchange will contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings. The use of an HIE means that essential health information is available for care team members even in the case of referrals the clinician may not be aware of, or for instances where the eligible hospital or CAH is contributing to the patient's record, but may not be the health care provider making the referral. In these instances, such transitions may or may not be able to be automatically identified by an EHR for inclusion in the denominators of the two existing measures associated with the HIE objective for the Promoting Interoperability Program (42 CFR 495.24(e)(6)). For example, consider a patient who has a hospital emergency room visit in January 2020 and receives a prescription, then goes to her primary care physician appointment in March 2020 without notifying the primary care physician of the hospital visit or the new medication. The primary care physician refers the patient to a specialist and the specialist receives and reconciles the patient's data from her primary care physician records. In this scenario, the hospital may not have had access to the patient's health record from the primary care physician, and the primary care physician and the specialist may not have access to the data from the hospital including essential information like an update to current medications.

Moreover, if the patient were to have another emergent issue and require emergency room care, the situation becomes further compounded. For this scenario, if the hospital, primary care physician, and specialist participated in a bi-directional exchange with a health information network, each health care provider from the hospital to the specialist would have access to all of the patient's records that may be critical for patient care and safety. Under the existing measures for the HIE objective (42 CFR 495.24(e)(6)), only the known transition of care from primary care physician to specialist would be included in the denominator. However, under the alternative measure for bi-directional exchange through a HIE that we are proposing, we would incentivize the eligible hospital or CAH to engage in health information exchange for care coordination that includes these additional transitions and referrals as well as other potential scenarios: Where the recipient of the transition of care may be unknown; where the eligible hospital or CAH may not be the referring health care provider; where the transition of care may happen outside the scope of the EHR reporting period. In this way, the eligible hospital or CAH's action to engage in bi-directional exchange through an HIE would allow each health care provider to contribute to the longitudinal care record in a manner that supports a wide range of transitions and referrals beyond those currently reflected in the measure denominators. This engagement supports robust health information exchange without placing burden on the hospital or the patient to be individually accountable to facilitate exchange via multiple (and potentially unknown) point-to-point connections.

The current COVID–19 public health emergency (PHE) has further highlighted the need to encourage interoperable HIE infrastructure and bi-directional exchange across the country that can ensure patients, health care providers, and public health authorities have the data they need to support quality care. In addition to supporting general care coordination, HIEs can specifically support the PHE response by facilitating enhanced use of telehealth and telemedicine through obtaining and aggregating patient information including when the patient's health care provider(s) may not be known.

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20537), we requested comment on whether eligible hospital or CAH participation in the Trusted Exchange Framework and Common Agreement (TEFCA) should be considered a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. TEFCA, which is currently under development, addresses the 21st Century Cures Act requirement to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' We received comments in support of this concept (83 FR 41669) although some disagreed indicating that they were concerned about adding additional burden.

Subsequently, in the CY 2021 PFS final rule (85 FR 84888 through 84893), we added an alternative measure for bi-directional exchange through a HIE under the Health Information Exchange objective for the MIPS Promoting Interoperability performance category beginning with the performance period in 2021. We are now proposing to add a similar measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022.

We are proposing to add the following new measure for inclusion in the Health Information Exchange objective at 42 CFR 495.24(e)(6)(ii)(C): Health Information Exchange (HIE) Bi-Directional Exchange measure. We propose to add this new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure 42 CFR 495.24(e)(6)(ii)(A) and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure 42 CFR 495.24(e)(6)(ii)(B). We are proposing that eligible hospitals and CAHs may either report the two existing measures and associated exclusions OR

[1435] Health Affairs, in press. Forthcoming analysis of survey conducted under Contract No. HHSP233201700049C, OMB Control No: 0955–0019.

[1436] ''Use of Certified Health IT and Methods to Enable Interoperability by U.S. Non-Federal Acute Care Hospitals, 2019'' ONC Data Brief No. 54, February 2021. See *https://www.healthit.gov/sites/default/files/page/2021-03/Hospital%20Use%20of%20Certified%20HIT_Interop%20v10_1.pdf.*

may choose to report the new measure and are proposing to revise 42 CFR 495.24(e)(6)(ii) to reflect this change. We propose that the HIE Bi-Directional Exchange measure would be worth 40 points. In no case could more than 40 points total be earned for the HIE objective. We are proposing the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response. As we believe that fulfillment of this measure is an extremely high value action, a ''yes'' response would enable eligible hospitals and CAHs to earn the 40 points allotted to the HIE objective. We propose that eligible hospitals and CAHs would attest to the following:

- Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.
- Using the functions of CEHRT to support bi-directional exchange with an HIE.

We believe it is appropriate for the new optional measure to serve as an alternative measure of performance on health information exchange since, in order to successfully meet the measure, an eligible hospital or CAH would be required to meet an overall standard of performance on health information exchange that is broader than the denominators and numerators of the current measures. To successfully attest to the new measure the eligible hospital or CAH must establish the technical capacity and workflows to engage in bi-directional exchange of information via an HIE for to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments during the EHR reporting period. This includes enabling the ability to query for or receive health information to occur for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR, as well as enabling sending or sharing information for these patients regardless of known referral or transition status, or the timing of any potential transition or referral. The proposed requirement to enable querying for or receiving health information for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments is broader than the current Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, which includes only new patients and known transitions or referrals received that occur during the EHR reporting period. Similarly, the proposed requirement to enable sending or sharing information for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments represents a broader scope than the current Support Electronic Referral Loops by Sending Health Information measure which includes only known transitions of care or referrals made that occur during the EHR reporting period. This proposed requirement is likewise more expansive than the denominators of either measure.

Relative to the numerators for the current measures, the new optional measure would require that bi-directional engagement be enabled for all unique patients admitted to or discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) and all unique patient records stored or maintained in the EHR for these departments during the EHR reporting without exclusion, exception, or allowances made for partial credit. This is similar to achieving a score of 100 percent on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure, while additionally completing required actions for additional exchange cases not included in the existing denominators. Finally, while we believe this optional measure would establish a high-performance standard with respect to information sharing, we also believe that availability of this optional measure would reduce current reporting burden associated with the program, as eligible hospitals or CAHs choosing to report on the measure would not be required to report on the two existing numerator/denominator measures.

While we believe there are a significant number of HIEs across the country that would meet the standards described in the attestation statements, some HIE arrangements may not have the capacity to enable bi-directional exchange for all unique patients, and thus would not meet the standard described in the attestation statements required to fulfill the measure. For instance, we would exclude exchange networks that only support information exchange between affiliated entities, such as health care providers that are part of a single health system, or networks that only facilitate sharing between health care providers that use the same EHR vendor.

To successfully attest to this measure, the eligible hospital or CAH must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE, which includes capabilities which support exchanging the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI). This is consistent with the existing measures under the Health Information Exchange objective, which require the use of CEHRT to create a C–CDA document, and support the exchange of the clinical data within the CCDS or the USCDI. We believe there are numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE. For instance, participants may interact with an HIE by using technology certified to the criterion at § 170.315(b)(1) to transmit C–CDAs to the HIE. Participants could also utilize API technology certified to either the criterion at § 170.315(g)(8) or (g)(10), as finalized in the ONC 21st Century Cures Act final rule (85 FR 25742), to enable an HIE to obtain data in the CCDS or USCDI from a participant's EHR. Additional certified health IT modules may also support exchange of information with an HIE for transitions of care, including modules certified to certification criteria at § 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at § 170.315(e)(1) ''View, download, and transmit to 3rd party'' which supports patient access to their information; and the certification criterion at § 170.315(g)(6) ''Consolidated CDA creation performance'' which supports creation of a summary of care record. We recognize that HIEs are currently

interacting with health care providers using certified health IT in a variety of ways, and believe that we should allow for substantial flexibility in how health care providers use certified health IT to exchange data using an HIE.

Furthermore, we wish to clarify that an eligible hospital or CAH attesting to these three statements would not be required to use all of the relevant certified health IT modules, as previously described, to support their connection with an HIE, nor must a connection with an HIE be solely based on certified health IT modules. For instance, a provider's EHR could generate a C–CDA using a certified health IT module, and subsequently transmit that document to an HIE using technology that is not part of a certified health IT module. Such an approach would be acceptable for attesting to the third proposed attestation statement requiring the use of CEHRT to support the measure.

We note that none of the actions required to attest to this measure are intended to conflict with a patient's rights or covered entities' (for example, health care providers) requirements/responsibilities under the HIPAA Privacy Rule, as set out at 45 CFR parts 160 and 164. We also understand that different HIEs that enable exchange in the manner described may have different policies related to confidentiality of patient information based on local circumstances and requirements. Nothing in the attestation statements for this measure are intended to conflict with individual HIE policies that may exist in these areas, or prevent eligible hospitals or CAHs from complying with these policies as a condition of their participation in the HIE.

We invite comments on this proposal, and whether commenters believe such an optional measure would incentivize eligible hospitals and CAHs to participate in HIEs while establishing a high performance standard for sharing information with other health care providers.

Finally, while our proposed attestation statements for this measure do not explicitly refer to participation in a health information network, or partnering with a health information network that participates in the Trusted Exchange Framework and Common Agreement (TEFCA) described in section 4003 of the 21st Century Cures Act, we recognize that this is likely to be an important way for eligible hospitals and CAHs to enable bi-directional health information exchange in the future. We will continue to explore ways to provide further guidance and/or update this measure to align with the use of health information networks that participate in the TEFCA in the future. For more information on current developments related to the TEFCA, we refer readers to *www.HealthIT.gov/TEFCA*.

6. Modifications to the Public Health and Clinical Data Exchange Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41637 through 41645, 41665 through 41667), for the Public Health and Clinical Data Exchange Objective, we finalized that eligible hospitals and CAHs must report on any two measures of their choice from the following 6 measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Clinical Data Registry Reporting; Electronic Case Reporting; Public Health Registry Reporting; and Electronic Reportable Laboratory Result Reporting. We also finalized that an eligible hospital or CAH must submit a yes/no response for any two measures to earn 10 points for the objective. Failure to report on two measures or submitting a ''no'' response for a measure will earn a score of zero. In addition, there are exclusions available for each of the measures. If an exclusion is claimed for one measure, but the eligible hospital or CAH submits a ''yes'' response for another measure, they would earn the 10 points for the Public Health and Clinical Data Exchange objective. If an eligible hospital or CAH claims exclusions for both measures they select to report on, the 10 points would be redistributed to the Provide Patients Electronic Access to Their Health Information measure under the Provider to Patient Exchange objective.

The Medicare Promoting Interoperability Program for eligible hospitals and CAHs has been an important mechanism for encouraging healthcare data exchange for public health purposes through the Public Health and Clinical Data Exchange Objective. But in an attempt to reduce burden, we previously stated our intention to propose in future rulemaking to remove the Public Health and Clinical Data Exchange objective and measures no later than CY 2022 (83 FR 41665). Many commenters strongly opposed this potential policy change noting that the inclusion of this objective incentivizes health care providers to share data with public health agencies (83 FR 41666). In response to these comments, we stated that we will continue to monitor the data we compile specific to the public health reporting requirements and take the commenters' concerns into consideration related to future actions (83 FR 41667). Effective responses to public health events, such as the COVID–19 PHE, require fast, accurate exchange of data between health care providers and Federal, State, and local public health agencies (PHAs). Health care providers collect these data for patient care and PHAs need them to protect the public, whether to track an outbreak, initiate contact tracing, find gaps in vaccine coverage, or pinpoint the source of a foodborne outbreak.

While our current approach has encouraged healthcare systems to stand up some of these capabilities, significant gaps remain, and in the absence of stronger incentives, it will be difficult to stand up the comprehensive data exchange needed for future public health response. Thus, we believe that a more assertive approach is needed.

b. Proposed Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective

In this section, we are proposing to require four of the measures associated with the Public Health and Clinical Data Exchange Objective, beginning with the EHR reporting period in CY 2022: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. We are proposing corresponding changes to the regulation text at 42 CFR 495.24(e)(8)(ii). These four measures would put PHAs on better footing for future health threats and a long-term COVID–19 pandemic recovery by strengthening three important public health functions: (1) Early warning surveillance, (2) case surveillance, and (3) vaccine uptake. Requiring these measures would enable nationwide syndromic surveillance for early warning of emerging outbreaks and threats; automated case and laboratory reporting for fast public health response; and local and national visibility on immunization uptake so PHAs can tailor vaccine distribution strategies.

(1) Syndromic Surveillance Reporting Measure

Syndromic surveillance provides PHAs with a timely way to detect, understand, and monitor health events using data from EHRs in emergency departments (EDs) and urgent care centers. By tracking patient symptoms and discharge diagnoses, PHAs have a strong early warning system that allows them to identify, monitor, characterize, and respond to novel and continuing

health events (for example, influenza, drug overdoses, vaping associated lung injuries, natural disasters, bioterrorism threats, and COVID–19) in near real time. Syndromic surveillance also provides real-time information for health events that are not supported by case reporting or laboratory reporting, such as injuries, suicidal ideation, non-reportable infectious diseases, and subtle health changes that are undiagnosed but can be detected by automated monitoring of chief complaint narratives and population-level trends. Syndromic surveillance relies on the secondary use of EHR data that supports delivery of care, enabling an efficient and cost-effective way to identify and characterize public health threats. The provision of these data requires no action from a health care provider, with data exchange automated from the EHR.

Syndromic surveillance has been critical for responding to the COVID–19 PHE, enabling situational awareness for decision makers at local, State, and national levels. The National Syndromic Surveillance Program (NSSP) is the primary mechanism for national-level syndromic surveillance in the United States. State and local stakeholders are critical end users and facilitate onboarding of hospitals, administering access to data, and monitoring data quality. CDC provides tools and assistance to facilitate these functions (for example, message mapping guides, standards, onboarding assistance, and data quality resources). As of February 1, 2021, nearly 6,000 healthcare facilities covering 49 states and the District of Columbia contribute data to NSSP, representing approximately 70% of all U.S. nonfederal EDs.[1437] Although some additional facilities report to local syndromic systems, and approximately 3 in 10 nonfederal hospitals are not participating in NSSP, there remain major gaps in syndromic surveillance coverage, leaving blind spots in the ability of State, local, and Federal PHAs to adequately prepare for emerging local and regional public health events.

We are proposing to make Syndromic Surveillance Reporting a required measure under the Public Health and Clinical Data Exchange Objective in the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022 to expand the coverage of syndromic surveillance to every region in the United States, help healthcare facilities and PHAs better prepare for emerging health events, and provide critical national early warning capabilities necessary for swift response and control of COVID–19 outbreaks. Requiring eligible hospitals and CAHs to report on participation in syndromic surveillance is anticipated to significantly increase hospital engagement with a PHA to submit syndromic data, particularly from the ED. The public health benefit of syndromic surveillance would be strengthened as the proportion of participating hospitals increases, that is, as more hospitals participate, there are more comprehensive and timely data with fewer gaps and the capability itself becomes better at detecting emerging threats. ED data are often the first indication of emerging health threats. As demonstrated with the COVID–19 pandemic, surveillance data from EDs often foreshadow a rise in the percent of persons testing positive, case incidence and deaths, and can focus assessments on relevant populations, such as age groups, racial or ethnic groups, persons experiencing homeless, persons with recent travel history, or recently vaccinated patients. Increased coverage would also improve coordination with PHAs providing hospitals with the ability to respond to the emergence of new health threats and modify their treatments, preparedness planning, and facility staffing accordingly. Converting the Syndromic Surveillance Reporting measure from optional to required would not pose a significant burden on hospitals; as 49 states are already participating in NSSP, the necessary infrastructure for wider adoption is already in place. More than two-thirds of nonfederal EDs participate in NSSP, demonstrating the feasibility of participation for a broad range of facilities and systems. Many nonparticipating facilities are part of larger health networks that have facilities already participating in NSSP.[1438] CDC's robust technical assistance program through NSSP and the network of State and local stakeholders would provide direct assistance to address technical challenges. While setting up the syndromic surveillance capability requires some initial implementation effort from the hospital, there is no significant ongoing burden, as the EHR vendor sets up and maintains the data feed.

In addition, upon further review of the current description for the Syndromic Surveillance Reporting measure, we believe the reporting requirement should include ED data only. Data from the ED setting are the most important based on clinical severity and there is existing infrastructure among hospitals and PHAs to make this a feasible policy to implement. While urgent care data are valuable, adding a requirement for reporting in that setting at this time could impose unnecessary burden on some healthcare facilities and PHAs.

The current description of this measure is as follows: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. We are proposing to change the setting for which data is required to be submitted from urgent care to the emergency department, place of service code 23, beginning with the EHR reporting period in CY 2022. We are proposing to codify this change at 42 CFR 495.24(e)(8)(ii)(A). We are also proposing that the first exclusion for this measure be modified to remove the reference to urgent care. The other two exclusions are unchanged. We propose to modify the first exclusion at 42 CFR 495.24(e)(8)(iii)(A)(1).

(2) Immunization Registry Reporting Measure

Immunizations are considered one of the ten great public health achievements and have resulted in declines in cases, hospitalizations, deaths, and health care costs associated with vaccine preventable diseases.[1439] The benefits and value of immunizations are realized when public policy, health systems, and community-based intervention efforts are working in coordination. Ensuring the coordination of these efforts can achieve high immunization coverage is dependent on the availability of timely, accurate, and complete information on vaccinations received by individuals in a population.

Immunization registries (also called immunization information systems or IIS) are powerful tools that allow collaboration between vaccine providers and public health agencies and enable coordination of population-based interventions. Immunization registries are confidential, population-based, computerized systems that record all vaccination doses administered by participating health care providers for individuals residing within a particular jurisdiction. At the point of clinical care, an immunization registry can provide consolidated immunization histories to assist vaccine providers in determining appropriate patient

[1437] Overview of the National Syndromic Surveillance Program (NSSP), *https://www.cdc.gov/nssp/overview.html.*

[1438] Overview of the National Syndromic Surveillance Program (NSSP), *https://www.cdc.gov/nssp/overview.html.*

[1439] Ten Great Public Health Achievements—United States, 2001–2010 (cdc.gov).

vaccinations. At the population level, immunization registries provide data on vaccination coverage assessment and program operations and in guiding public health action to improve vaccination rates.

Currently, 50 states, the District of Columbia, 8 island territories, and 3 cities (New York City, Philadelphia, and San Diego) operate an immunization registry. CDC provides technical assistance and nationwide leadership to all State immunization registries to ensure the optimal use of immunization registries for determining vaccination coverage at local, State, and national levels. Immunization registries already have connections in place to capture administered doses in real-time for a substantial portion of the population, a process accelerated over the last eight years by the Promoting Interoperability Programs. According to data from the most recent CDC IIS Annual Report (2019) available, immunization registries currently hold demographics and immunization data on 95% of children 0–6 years, 82% of adolescents, and 60% of adults.[1440] While each State Immunization registry currently coordinates with health care providers and EHR systems to achieve interoperability and facilitate immunization reporting, varying State reporting policies limit the completeness and timeliness of records in immunization registries and the optimal use of immunization registries for determining vaccination coverage.

We are proposing to make the Immunization Registry Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022 as it is critical for understanding vaccination coverage both at the jurisdiction level and nationwide and identifying where additional vaccination efforts are needed. Making standardized reporting to an immunization registry a required measure would provide an immediate benefit by increasing the COVID–19 vaccination records reported to these systems. Making the measure required would also improve the data quality of records in immunization registries and facilitate use of immunization registries for clinical decision support and tracking of vaccine administration and distribution.

We believe that making the Immunization Registry Reporting measure required, compared to the current option to choose this measure as one of two among six measures, would increase the reporting of immunization data by health care providers to public health agencies. Making the measure required is also critical for the COVID–19 vaccination response because it would provide a better view of the vaccines administered and distributed at national, State and local levels. This is a function immunization registries currently provide for all public vaccines, but would be particularly important for COVID–19 vaccines. In addition to the COVID–19 vaccination response, there is an equally important need for routine vaccination coverage to increase. Fear of COVID–19 has caused deferrals of routine vaccinations as patients limit their interactions, including with their family doctors. More complete data in immunization registries as a result of the required measure would also optimize the use of immunization registries to determine who has not been vaccinated, pockets of under vaccination, and identifying where interventions should be focused for routine and emergency response vaccines. Requiring the measure would reduce the regulatory and administrative burden health care providers experience when exchanging information with immunization registries.

We are not proposing any changes to the description of the measure including any of the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(B).

(3) Electronic Case Reporting

Healthcare providers are required by State law to report certain diseases and conditions, a process called *case reporting,* which provides PHAs with data on approximately 120 diseases and conditions of public health significance.[1441] Case reporting is a vital and long-standing tool that PHAs use to prevent the spread of infectious diseases. Case reporting serves as early notification to PHAs for potential outbreaks, and includes information that enables PHAs to start contact tracing and other prevention measures. Case reports also include critical clinical information that would not be included in syndromic surveillance or laboratory reporting, and can help to illuminate the impact of comorbidities, treatments, and variable access to care. Information from the case reports can be used to further work on social determinants of health and ensure equal access to preventative care across populations. Electronic case reporting is the automated, real-time, bi-directional exchange of case report information between EHRs and PHAs. Electronic case reporting uses standard codes to trigger the transfer of relevant clinical data to PHAs for case investigation and follow-up. As of March 2021, most states do not require electronic submission of case reports as part of their regulations and case reporting often occurs through outdated manual methods (for example, fax, email, or phone), which results in delays, underreporting, and incomplete or inaccurate case data. Manual case reporting also imposes burdens on health care providers, taking staff time away from patients to submit case reports and comply with State reporting requirements. Electronic case reporting allows health care providers to fulfill mandated public health reporting requirements without imposing additional burden and disrupting the clinical workflow. This automated data exchange facilitates faster and more efficient disease tracking, case management, and contact tracing. Electronic case reporting provides more timely and complete data than manual reporting, including data on demographics, comorbidities, immunizations, medications, occupation, and other treatments.

Recent efforts by the CDC have sought to significantly improve the effectiveness of electronic case reporting through eCR Now, a strategic initiative that allows for rapid adoption and implementation of electronic case reporting for COVID–19 (*https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting.html*). As part of this initiative, CDC and its partners have developed an eCR Now FHIR® API to establish electronic case reporting capability in EHR systems. The initiative also supports an electronic case reporting infrastructure that is helping to advance interoperability. This infrastructure supports sending electronic case reports to a shared service platform, and not directly to a PHA, which means that any health care provider that has established an electronic case reporting connection also has a connection with every State PHA, many large local health departments and some territories. This promotes nationwide interoperability and increases the availability of data for patients who may be traveling or spending time away from their home State. For example, if a patient is a resident of one State but seeks care in another State, this infrastructure will automatically route the case report to

[1440] *https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/2019-data.html.*

[1441] CSTE State Reportable Condition Assessment page: *https://www.cste.org/page/SRCA.*

both states that would have jurisdiction over this report. This increases inter-jurisdictional reporting, allowing for more seamless case investigation at the national level. The interoperable infrastructure and the use of a standard data format also reduces the variability of case report forms across conditions and jurisdictions, streamlining reporting forms for EHR vendors and health care providers.

As a result of the CDC effort to scale up eCR Now for COVID–19, all 50 states, the District of Columbia, Puerto Rico and 11 large local jurisdictions have connected to the eCR Now shared services platform and are currently receiving electronic case reports, with more than 7,200 healthcare facilities on board and 7.1 million reports for COVID–19 received by PHAs as of March 8, 2021.[1442] The eCR infrastructure is designed to rapidly scale for PHEs, such as COVID–19, but it is also enabled to currently support data transmission for 99 reportable and notifiable conditions. While these are significant advancements, the piecemeal approach of encouraging adoption of these tools by individual health care providers has not been an effective or efficient means to quickly scale this effort nationally as has been needed for the COVID–19 PHE response.

We believe the uneven adoption of electronic case reporting creates a public health vulnerability. We are proposing to make the Electronic Case Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022. We believe making this a required measure would accelerate development of electronic case reporting capabilities in EHR systems, reduce healthcare administrative burden of complying with State-mandated disease reporting requirements, provide regulatory clarity for EHR vendors, and improve the timeliness, completeness, and utility of case report data for PHAs. We believe that requiring the Electronic Case Reporting measure would be feasible and beneficial for eligible hospitals and CAHs. This change would encourage EHR vendors to make electronic case reporting available to their customers, which would make adoption of this capability relatively straightforward for eligible hospitals and CAHs. As described in the EHR Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62888), for purposes of this measure, eligible hospitals and CAHs must use a health IT module certified to the ''Transmission to public health agencies—electronic case reporting'' certification criterion at 45 CFR 170.315(f)(5) which relates to how the health IT uses structured data within an EHR to trigger or indicate the generation of an electronic initial case report.[1443] Eligible hospitals and CAHs may then transmit the report in the manner specified by the case reporting requirements of the entity to which they are transmitting a report.

We believe that requiring the Electronic Case Reporting measure would provide certainty to EHR vendors and facilitate an organized and industry-wide rollout of electronic case reporting capabilities.

We are not proposing any changes to the description of the Electronic Case Reporting measure and the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(C) will remain available.

(4) Electronic Reportable Laboratory Result Reporting Measure

State laws and regulations require laboratories to report certain diseases and conditions identified by testing to State and local PHAs. Electronic laboratory reporting (ELR) is the automated transmission of reports from laboratories to State and local PHAs. ELR produces faster and more complete information than manual reporting, reduces the burden of submission to PHAs, and eliminates opportunities for data entry error. ELR facilitates efficient case investigation, contact tracing, identification of hot spots, and other core public health functions. Because ELR requires essential fields, PHAs are less likely to request follow up information when receiving reports via ELR feeds, further reducing burden on laboratories.

Prior to the COVID–19 pandemic, more than 90% of laboratory reports sent to PHAs were submitted via ELR; the bulk of this reporting came from commercial laboratories. Hospital laboratories were less likely to utilize ELR data feeds relative to commercial laboratories, relying on other means to report results. The COVID–19 pandemic posed a tremendous challenge to the nation's laboratory and testing infrastructure, and rates of ELR to PHAs declined as COVID–19 testing increased, a multitude of tests (for example, point-of-care tests) entered the market, and non-traditional testing sites (for example, drive thru testing sites) where ELR is not available were utilized. Throughout the pandemic, the subset of hospital laboratories, while still a relatively small portion of overall testing volume, continued to lag in ELR implementation relative to larger commercial and clinical laboratories. A CDC-Association of Public Health Laboratories (APHL) collaboration has enabled the reporting of COVID–19 laboratory data through the APHL Informatics Messaging Services (AIMS) platform. Using AIMS, PHAs can submit essential data to CDC for detailed analysis, visualization, and surveillance, providing a national snapshot of the testing landscape and informing Federal response efforts. Section 18115 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act and HHS implementing guidance require all laboratories conducting testing for SARS–CoV–2 to report results to a State or local public health agency (which then report these data to CDC). The HHS implementing guidance allows for reporting using multiple potential methods, including ELR. All State PHAs are capable of and are receiving ELR for notifiable conditions.

We are proposing to make the Electronic Reportable Laboratory Result Reporting measure a required measure under the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2022. We believe that making this measure required would spur hospital laboratories to adopt this capability, increase the timeliness and completeness of laboratory reporting to PHAs, strengthen the effectiveness of prevention and control measures, reduce the burden of reporting by laboratory staff, and aid in laboratory compliance with the requirements of section 18115 of the CARES Act as well as future PHEs. Requiring the Electronic Reportable Laboratory Result Reporting measure would incentivize the minority of hospital laboratories that have not adopted ELR to upgrade to this essential capability. With the availability of the APHL AIMS platform, HIEs, and other mechanisms, there is a diversity of options for eligible hospitals and CAHs to establish an ELR channel with a PHA to feasibly implement this requirement. In addition, CDC-provided ELR technical assistance is also available, further reducing implementation barriers.

We are not proposing to change the description of the Electronic Reportable Laboratory Result Reporting measure

[1442] Healthcare Facilities in Production for COVID–19 Electronic Case Reporting | CDC.

[1443] For more information about this certification criterion, please see the Certification Companion Guide at *https://www.healthit.gov/test-method/transmission-public-health-agencies-electronic-case-reporting.*

and the exclusions that we established at 42 CFR 495.24(e)(8)(iii)(F) will remain available.

7. Proposed Scoring of the Public Health and Clinical Data Exchange Objective

We are proposing that, beginning with the EHR reporting period in CY 2022, an eligible hospital or CAH would receive 10 points for the Public Health and Clinical Data Exchange objective if they report a ''yes'' response for each of the following 4 required measures: Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting. In the event an eligible hospital or CAH is able to claim an exclusion for three or fewer of these four required measures, we are proposing they would receive 10 points for the objective if they report a ''yes'' response for one or more of these measures and claim applicable exclusions for which they qualify for the remaining measures. If the eligible hospital or CAH fails to report on any one of the four measures required for this objective or reports a ''no'' response for one or more of these measures, we are proposing the eligible hospital or CAH would receive a score of zero for the Public Health and Clinical Data Exchange objective, and a total score of zero for the Medicare Promoting Interoperability Program. If an eligible hospital or CAH claims applicable exclusions for which they qualify for all four required measures, we propose to redistribute the points associated with the objective to the Provider to Patient Exchange objective. We are proposing corresponding changes to 42 CFR 495.24(e)(8)(ii) and (iii) to reflect these proposals.

We are proposing to retain the Public Health Registry Reporting and Clinical Data Registry Reporting measures and to make them optional and available for bonus points beginning with the EHR reporting period in CY 2022. We are proposing an eligible hospital or CAH may earn a maximum of 5 bonus points if they report a ''yes'' response for either the Public Health Registry Reporting measure OR the Clinical Data Registry Reporting measure. We are proposing to further modify 42 CFR 495.24(e)(8)(ii) to add: Eligible hospitals and CAHs could receive a bonus of 5 points for this objective if they report the measures specified under 42 CFR 495.24(e)(8)(iii)(D) or (E).

In connection with our proposal to make these measures optional, we are proposing the three exclusions that we established for each measure would no longer be available beginning with the EHR reporting period in 2022. For the Public Health Registry Reporting measure, we are proposing to revise 42 CFR 495.24(e)(8)(iii)(D), and for the Clinical Data Registry Reporting measure we are proposing to revise 42 CFR 495.24(e)(8)(iii)(E).

8. SAFER Guides

a. Background

ONC developed and released the Safety Assurance Factors for EHR Resilience Guides (SAFER Guides) in 2014, and later updated them in 2016. This series of nine user guides support hospitals' ability to address EHR safety.[1444] Collectively, the SAFER Guides help healthcare organizations to conduct self-assessments to optimize the safety and safe use of EHRs in the three areas listed in this rule, in Table IX.F.-01. The SAFER Guides were intended to be utilized by EHR users, developers, patient safety organizations, and those who are concerned with optimizing the safe use of Health IT. By completing a self-assessment using the SAFER Guides, providers can help to develop a ''culture of safety'' within their organizations and ensure they are responsible operators of technology tools, including certified health IT products, which they utilize in the delivery of care. The SAFER Guides are based on the best evidence available at the time of publication, including a literature review, expert opinion, and field-testing at a wide range of healthcare organizations, from small ambulatory care practices to large health systems.

In the FY 2019 IPPS/LTCH final rule (83 FR 41663), commenters expressed concern with having the ability to maintain continuous electronic connectivity, and identified a need to account for planned and unplanned system outages or downtime. In response, we referred readers to the SAFER Guides, to utilize and incorporate as a part of their emergency planning processes. In the case of system disruption, failure, or natural disaster, the SAFER Guides provide recommended safety practices during planned or unplanned EHR unavailability, where end users are unable to access all or part of their EHR. Also included are back-up procedures to prevent the potential loss of clinical and administrative data, and how to utilize paper charting during such downtime (83 FR 41663). We believe that conducting annual self-assessments based on the SAFER Guides' recommendations would satisfy stakeholder feedback received through the Annual Call for Measures and through public comment (83 FR 41663), supporting alternative and consistent safety practices for EHR users. We also believe requiring eligible hospitals and CAHs to conduct an annual self-assessment using the SAFER Guides would support the goals of improved EHR use and health care quality, as described in section 1886(n)(3)(A) of the Act.

[1444] *https://www.healthit.gov/topic/safety/safer-guides.*

Table IX.F.-01. The SAFER Guides

Foundational Guides	- High Priority Practices - Organizational Responsibilities
Infrastructure Guides	- Contingency Planning - System Configuration - System Interfaces
Clinical Process Guides	- Patient Identification - Computerized Provider Order Entry with Decision Support - Test Results Reporting with Follow-Up - Clinician Communication

b. Proposed New SAFER Guides Measure

We are proposing to add a new SAFER Guides measure to the Protect Patient Health Information objective beginning with the CY 2022 EHR reporting period. For this measure, we are proposing that an eligible hospital or CAH must attest to having conducted an annual self-assessment of all nine SAFER Guides (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the EHR reporting period occurs, with one ''yes/no'' attestation statement accounting for a complete self-assessment using all nine guides. We propose that in CY 2022, this measure would be required, but it would not be scored, and that reporting ''yes'' or ''no'' will not affect the total score for the Medicare Promoting Interoperability Program. We are also proposing to add corresponding regulatory text for this measure at § 495.24(e)(4)(ii) and (iv).

In order to complete a ''self-assessment'' of the SAFER Guides we would expect that each eligible hospital or CAH would complete the checklist of recommended practices included at the beginning of each SAFER Guide. Following the checklist, a practice worksheet provides the rationale for, and examples of, how to implement each recommended practice, likely sources of input into the assessment of each practice, and fillable fields to record follow-up actions.

We understand that every organization faces unique circumstances, and will implement a particular safety practice differently. As a result, some of the specific examples in the SAFER Guides for recommended practices may not be applicable to every organization. We note that a ''self-assessment'' does not require an organization to confirm that it has implemented ''fully in all areas'' each practice described in a particular SAFER guide, nor will an organization be scored on how many of the practices the organization has fully implemented. Rather, the intent of this proposed requirement is for eligible hospitals and CAHs to regularly assess their progress and status on important facets of patient safety.

The recommended practices in the SAFER Guides are intended to be useful for all EHR users. However, we recognize that the individuals responsible for the proposed annual self-assessment may vary across organizations. An optimal team for completing an annual review of the SAFER Guides might include representatives from an eligible hospital or CAHs clinical leadership, nursing staff, pharmacy representatives, and the staff responsible for implementing and maintaining both internal technology systems as well as data connections with external partners, such as an HIE.

Regarding the frequency of self-assessments using the SAFER Guides, we are proposing that a eligible hospital or CAH must attest to completing their self-assessment using the SAFER Guides on an annual basis, following an initial completion of the self-assessment (some organizations may have already completed a self-assessment using the SAFER Guides prior to implementation of this requirement, if finalized). We would expect providers to revisit this assessment to determine whether any changes have occurred for their organization. We believe that requiring eligible hospitals and CAHs to periodically review this self-assessment as proposed would support a stronger culture of change management within organizations participating in the Medicare Promoting Interoperability Program, and would assist organizations in actively understanding and addressing potential safety vulnerabilities, which may significantly impact an organization's safety posture. We recognize that organizations may be at different stages in their progress towards assessing patient safety vulnerabilities and that hospitals vary in the resources that they could devote to annual self-assessment using the Guides. Gathering this information may be time consuming for small or rural hospitals that have contracted out some implementation services and may not have expertise available on staff to complete a full self-assessment using the SAFER Guides. For eligible hospitals and CAHs with less experience in these areas, we note that there are a number of resources available, which may be able to assist with completing a self-assessment.

We are inviting public comment on these proposals.

9. Actions To Limit or Restrict the Compatibility or Interoperability of CEHRT

a. Background

Section 106(b)(2) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) includes the heading ''Preventing Blocking The Sharing Of Information.'' Section 106(b)(2)(B) amended section 1886(n)(3)(A)(ii) of the Act for eligible hospitals and, by extension, section 1814(l)(3) of the Act for CAHs to require that a hospital demonstrates (through a process specified by the Secretary, such as the use of an attestation) that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology. To implement these provisions, we established and codified at 42 CFR 495.40(b)(2)(i)(I) attestation requirements for the Promoting Interoperability Programs to support the ''prevention of information blocking,'' which consist of three statements containing specific representations about a health care provider's implementation and use of CEHRT. For further discussion on these

requirements, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77028 through 77035) and the Interoperability and patient access final rule (85 FR 25578 through 25580). The attestation statements finalized for eligible hospitals and CAHs at 42 CFR 495.40(b)(2)(i)(I) are:

- *Statement 1:* Did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.
- *Statement 2:* Implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the certified EHR technology was, at all relevant times: (1) Connected in accordance with applicable law; (2) compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR part 170; (3) Implemented in a manner that allowed for timely access by patients to their electronic health information; and (4) Implemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate certified EHR technology and vendors.
- *Statement 3:* Responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj(3)), and other persons, regardless of the requestor's affiliation or technology vendor.

Participants in the Medicare Promoting Interoperability Program that are required to attest to the three statements under 42 CFR 495.40(b)(2)(i)(I) are also subject to public reporting as established in the Patient Access and Interoperability final rule (85 FR 25578 through 25580). Under this policy, we will post information on a CMS website available to the public for eligible hospitals and CAHs who have attested ''no'' to any of these three statements. Section 4004 of the 21st Century Cures Act added section 3022 to the Public Health Service Act (PHSA) (the ''PHSA information blocking provision''), which describes practices by health care providers, health IT developers, and health information exchanges and networks, that constitute information blocking, and provides for civil monetary penalties and other disincentives for those who engage in information blocking. In the ONC 21st Century Cures Act final rule published in the **Federal Register** on May 1, 2020, ONC finalized a definition of information blocking and identified reasonable and necessary activities (''exceptions'') that do not constitute information blocking (85 FR 25642). For health care providers (as defined in 42 U.S.C. 300jj) ''information blocking means a practice that (1) Except as required by law or covered by an exception [. . .], is likely to interfere with access, exchange, or use of electronic health information; and if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information'' (45 CFR 171.103).

The Cures Act provides for civil monetary penalties for any individual or entity that is a developer, network, or exchange that has committed information blocking (see section 3022(b)(2)(A) of the PHSA). Regarding health care providers, the Cures Act provides that ''Any [health care provider] determined by the [HHS] Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking'' (section 3022(b)(2)(B) of the PHSA). For more information about the information blocking policies finalized in the ONC 21st Century Cures Act final rule, see *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking.*

b. Proposed Changes to the Attestation Statements

Although there could be some degree of overlap between conduct described in the attestation statements under 42 CFR 495.40(b)(2)(i)(I) and conduct that could be considered information blocking under section 3022 of the PHSA and ONC's implementing regulations at 45 CFR 171.103, it is important to note these are separate and distinct authorities. For instance, the ONC 21st Century Cures Act final rule finalized a definition for what constitutes information blocking, and exceptions to information blocking that are not reflected in the previously finalized attestation statements under 42 CFR 495.40(b)(2)(i)(I). While we previously stated in the 2017 QPP final rule that these attestations statements did not impose ''unnecessary or unreasonable requirements'' on health care providers (81 FR 77029), after careful review of these statements in light of the information blocking regulations at 45 CFR part 171, we believe that statements 2 and 3 are no longer necessary. Thus, beginning with the CY 2022 EHR reporting period, we are proposing at 42 CFR 495.40(b)(2)(i)(I) and (J) to no longer require statements 2 and 3. We believe that the similarities between practices described under statements 2 and 3, and the practices that could constitute information blocking under section 3022 of the PHSA and ONC's implementing regulations will create confusion for stakeholders. To this point, the practices that could constitute information blocking under 45 CFR part 171 are much broader than those described in the attestation statements. We discuss specific instances of potential confusion in this proposed rule.

Statement 2 requires attestation to a series of statements regarding the use of certified technology and a designated manner for implementing certified technology. For instance, attestations to the implementation of technology compliant with the standards for certified health IT at 45 CFR part 170, and use of functionality to support health information exchange with other providers. However, as previously noted, the definition of information blocking finalized in the ONC 21st Century Cures Act final rule is not specific to, nor limited to, the use of certified technology which is compliant with certain standards or the use of certain functionality. Under the ONC 21st Century Cures Act final rule, a health care provider may still be determined to have engaged in practices likely to interfere with access, exchange, or use of electronic health information (information blocking) regardless of whether they are using certified technology.

Regarding statement 3, we stated in the 2017 QPP final rule that ''technical, legal, and other practical constraints may prevent a health care provider from responding to some requests to access, exchange, or use electronic health information in a health care provider's certified EHR technology'' (81 FR 77033). Subsequently, in the ONC 21st Century Cures Act final rule, ONC established a set of reasonable and necessary activities that are not considered information blocking when responding to a request for EHI. The reasonable and necessary activities established under the ONC 21st Century Cures Act final rule now provide more specific direction to providers when responding to a request for EHI than the general ''technical, legal, and other practical constraints'' which we

described in the QPP 2017 final rule with regards to statement 3. Accordingly, we believe that continuing to require statement 3 may introduce confusion for those health care providers who are obligated to comply with the regulations finalized in the ONC 21st Century Cures Act final rule when responding to a request for EHI.

In order to distinguish the attestation required by section 106(b)(2)(B) of MACRA from information blocking under section 3022 of the PHSA, we are proposing to modify the heading of the regulation text at 42 CFR 495.40(b)(2)(i)(I) and the definition of ''meaningful EHR user'' under 495.4 from ''Support for health information exchange and the prevention of information blocking'' to ''Actions to limit or restrict the compatibility or interoperability of CEHRT,'' which reflects the language used in section 106(b)(2)(B) of MACRA.

We invite public comment on our proposals.

For ease of reference, Table IX.F.-02 lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2022 as revised to reflect the proposals made in this proposed rule. Table IX.F.-03 lists the 2015 Edition certification criteria required to meet the objectives and measures.

TABLE IX.F.-02: Proposed Objectives and Measures for the Medicare Promoting Interoperability Program in 2022

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing	e-Prescribing: For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are queried for a drug formulary and transmitted electronically using certified electronic health record technology (CEHRT).	The number of prescriptions in the denominator generated, queried for a drug formulary, and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their electronic health record (EHR) reporting period.
Electronic Prescribing	Query of Prescription Drug Monitoring Program (PDMP) (bonus): For at least one Schedule II opioid electronically prescribed using certified electronic health record technology (CEHRT) during the electronic health record (EHR) reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the electronic health record (EHR) reporting period for which the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) was the transitioning	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	their patient to another setting of care or provider of care: (1) Creates a summary of care record using certified electronic health record technology (CEHRT); and (2) electronically exchanges the summary of care record.		or referring provider.	
Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received for patient encounters during the electronic health record (EHR) reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using certified electronic health record technology (CEHRT) for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	N/A
Health	Engagement in Bi-	N/A (measure is Y/N)	N/A (measure is Y/N)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
Information Exchange	Directional Exchange Through Health Information Exchange (HIE) (Alternative to two previous HIE measure)			
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit his or her health information; and the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interfaces (API) in the eligible hospital or CAHs certified electronic health record technology (CEHRT).	The number of patients in the denominator (or patient authorized representative) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospitals or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by their jurisdiction's immunization registry or IIS during the electronic health record (EHR) reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency department.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the electronic health record (EHR) reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of six months prior to the start of the EHR reporting period.

Objective	Measure	Numerator	Denominator	Exclusion
Public Health and Clinical Data Exchange	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the electronic health record (EHR) reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHS has declared readiness to receive electronic case reporting data as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Electronic Reportable Laboratory (ELR) Result Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit ELR results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in their jurisdiction during the electronic health record (EHR) reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific ELR standards required to meet the certified electronic health record technology (CEHRT) definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive ELR results from an eligible hospital or CAH as of six months prior to the start of the EHR reporting period.
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active	N/A (measure is Y/N)	N/A (measure is Y/N)	none

Objective	Measure	Numerator	Denominator	Exclusion
	engagement with a public health agency (PHA) to submit data to public health registries.			
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry (CDR).	N/A (measure is Y/N)	N/A (measure is Y/N)	none
Protect Patient Health Information	Security Risk Assessment	N/A (measure is Y/N)	N/A (measure is Y/N)	none
Protect Patient Health Information	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	N/A (measure is Y/N)	N/A (measure is Y/N))	none

TABLE IX.F.-03: Medicare Promoting Interoperability Program Objectives and Measures, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation

Health Information Exchange (alternative)	Health Information Exchange (HIE) Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting § 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible professionals, and eligible hospitals and CAHs	§ 170.315(c)(1) § 170.315(c)(2) § 170.315(c)(3)(i) and (ii) § 170.315(c)(4) (optional)
Protect Patient Health Information	Security Risk Assessment	§ 164.308 (a)(1)
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	None

10. Proposed Changes to the Scoring Methodology for the EHR Reporting Period in CY 2022

a. Proposed Performance-Based Scoring Threshold Increase

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41645), we adopted a new performance-based scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program which included a minimum scoring threshold which eligible hospitals and CAHs must meet in order to satisfy the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24. We established at 42 CFR 495.24(e)(1)(i) that eligible hospitals and CAHs must earn a total score of at least 50 points on the objectives and measures to be considered a meaningful EHR user.

The Medicare Promoting Interoperability Program's performance results from CY 2019 (the first full year of programmatic data demonstrating the new performance-based scoring methodology) revealed that 3,776 of 3,828 participating eligible hospitals and CAHs that reported to the program successfully met the minimum threshold score of 50 points.

For CY 2022 and subsequent years, we are proposing to increase the minimum scoring threshold from 50 points to 60 points, and proposing corresponding changes to the regulation text at 42 CFR 495.24(e)(1)(i)(C). Given the widespread success of participating hospitals in CY 2019, we believe that such program results signify the need for raising the minimum score for CY 2022. We note that eligible hospitals and CAHs will have gained two more years of experience in the Medicare Promoting Interoperability Program (CYs 2020 and 2021) at the 50 point minimum score threshold to improve performance. This increase from 50 points to 60 points represents our intent to heighten the required standards for the Medicare Promoting Interoperability Program's performance levels and encourage higher levels of performance through the advanced usage of CEHRT in order to further incentivize eligible hospitals and CAHs to improve interoperability and health information exchange.

We seek comments on our proposal to increase the minimum scoring threshold from 50 to 60 points.

b. Performance-Based Scoring Methodology Table Updates

The following table reflects the objectives and measures for CY 2022 if the proposed changes discussed in this section are finalized, including the optional Query of PDMP measure worth 10 bonus points, the adoption of a new alternative Health Information Exchange Bi-Directional Exchange measure, the adoption of a SAFER Guides measure, and modified requirements for the Public Health and Clinical Data Exchange objective.

Table IX.F.-04: Performance-Based Scoring Methodology EHR Reporting Period in CY 2022

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information*	40 points
Public Health and Clinical Data Exchange	Report the following 4 measures:* • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

*Signifies a proposal made in this FY 2022 IPPS/LTCH proposed rule.

11. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Proposed Changes to Clinical Quality Measures in Alignment With the Hospital IQR Program

(1) Background

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (referred to as CQMs or eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program.

The following table lists previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program (84 FR 42597 through 42599) for the reporting period in CY 2021 and in subsequent years. The table includes the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e) which we finalized as mandatory for reporting beginning with CY 2022 (84 FR 42598 through 42600).

Table IX.F.-04: CQMs for Eligible Hospitals and CAHs for CY 2021 and Subsequent Years

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

(2) Proposed eCQM Removals

As we discuss in the Hospital IQR Program section of this proposed rule, we are proposing to remove four eCQMs from the Hospital IQR Program's measure set effective for the CY 2024 reporting period/FY 2026 payment determination. Specifically, we are proposing to remove:

- STK–03 (Anticoagulation Therapy for Atrial Fibrillation/Flutter),
- STK–06 (Discharged on Statin Medication),
- PC–05 (Exclusive Breast Milk Feeding), and
- ED–2 (Admit Decision Time to ED Departure Time for Admitted Patients).

We refer readers to section IX.C. of the preamble of this proposed rule for additional discussion of the rationales for these proposed removals from the Hospital IQR Program.

We continue to believe that aligning the CQM requirements that we adopt in the Medicare Promoting Interoperability Program with the Hospital IQR Program's eCQM requirements benefits hospitals that are working to comply with each program's requirements. Aligning the requirements and measure sets across programs promotes efficiency and harmonizes with our goal of applying a parsimonious set of the most meaningful measures available to track patient outcomes and impact. We believe that maintaining alignment between the Hospital IQR Program and the Medicare Promoting Interoperability Program streamlines our approach to data collection, calculation, and reporting using EHRs. We further believe that this streamlined approach allows us to leverage clinical and patient-centered information for measurement, improvement, and learning.

To maintain this alignment between the Hospital IQR Program and Medicare Promoting Interoperability Program, and for the reasons described in section IX.C. of the preamble to this proposed rule, we propose to remove STK–03, STK–06, PC–05, and ED–2 from the previously finalized set of eCQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2024.

We welcome public comments on these proposed eCQM removals.

(3) Proposed eCQM Adoptions

As we have stated previously in rulemaking (82 FR 38479), we plan to continue to align the CQM reporting requirements for the Promoting Interoperability Program with similar requirements under the Hospital IQR Program. Further, as we discuss in section IX.C of the preamble of this proposed rule, we are proposing to adopt two new eCQMs in the Hospital IQR Program beginning with the CY 2023 reporting period/FY 2025 payment determination:

- Hospital Harm—Severe Hypoglycemia (NQF #3503e), and
- Hospital Harm—Severe Hyperglycemia (NQF #3533e).

We refer readers to section IX.C of the preamble of this proposed rule for additional discussion of the technical details associated with these measures,

their data sources, calculations, cohorts, and risk adjustment.

As previously discussed, with respect to proposed eCQM removals, we continue to believe that adopting aligned requirements between the Hospital IQR and Medicare Promoting Interoperability Program is beneficial to participating hospitals. To maintain this alignment and to support hospitals' ability to choose amongst a consistent pool of CQMs, as well as the clinical importance of these measures as discussed in section IX.C. of the preamble to this proposed, we propose to adopt the Severe Hypoglycemia and Severe Hyperglycemia CQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2023.

We welcome public comments on these proposed eCQM adoptions.

Table IX.F-06: CQMs for Eligible Hospitals and CAHs for CY 2022

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

Table IX.F.-07: CQMs for Eligible Hospitals and CAHs for CY 2023

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

Table IX.F.-08: CQMs for Eligible Hospitals and CAHs for CY 2024 and Subsequent Years

Short Name	Measure Name	NQF No.
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

(4) Proposed Updates to Certification Requirements for eCQM Reporting—2015 Edition Cures Update

In the ONC 21st Century Cures Act final rule, ONC revised the clinical quality measurement criterion at § 170.315(c)(3) to refer to CMS QRDA Implementation Guides and remove the Health Level 7 (HL7®) QRDA standard from the relevant health IT certification criteria (85 FR 25686). In the Information Blocking and ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency interim final rule with comment period (85 FR 70064), ONC finalized that health IT developers will have until December 31, 2022, to make updated certified technology available in accordance with the revised criteria (85 FR 70066 through 70068). The revision was responsive to industry feedback that the health IT certified to the prior ''CQMs-report'' criterion was only primarily being used to submit eCQMs for CMS reporting programs. These updates were finalized to reduce burden on health IT developers under the ONC Health IT certification program and have no impact on providers' existing reporting practices for CMS programs.

In this proposed rule, we are proposing to require eligible hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25667) to submit data for eCQMs, beginning with the reporting period in CY 2023. This is in alignment with the proposal for the Hospital IQR Program discussed in section IX.C. of the preamble of this proposed rule. We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25666 through 25668). We also refer readers to the CY 2021 PFS final rule for the Medicare Promoting Interoperability Program (85 FR 84815 through 84825) and the Hospital IQR Program (85 FR 84825 through 84828), and section IX.C. of the preamble of this proposed rule for additional information related to this proposal.

We invite public comment on our proposal to require hospitals and CAHs to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for eCQMs, beginning with the reporting period in CY 2023, in alignment with the Hospital IQR Program proposal.

(5) References to Additional Requests for Information

We also refer readers to section IX.A of the preamble of this proposed rule where we request information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward use of the Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard. Additionally, we refer readers to section IX.B of the preamble of this proposed rule where we request information on the possibility of expanding our current social disparities methods in order to include race and ethnicity as well as seeking comment on the potential design of a hospital equity score for calculating results across multiple social risk factors and measures.

12. Requests for Information

a. Request for Information on Additional Objectives or Measures Adopting FHIR®-Based API Standards

Fast Healthcare Interoperability Resources (FHIR®) (*http://hl7.org/fhir*) is a free and open-source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health IT. FHIR® allows systems to communicate and information to be shared seamlessly with a lower burden on stakeholders. Through the HL7® FHIR® standard, cost and burden for health care providers and patients are reduced since it simplifies implementation without sacrificing information integrity, and establishes fast, efficient, and flexible health data exchange as a stand-alone standard or combined with existing standards. Essentially, HL7®'s FHIR® standard framework provides an interoperable platform for a variety of healthcare data by defining a standard way to structure this information as 'resources' and allows the developer-friendly automated data-exchange to occur via APIs. The use of APIs utilizing the FHIR® standard has the potential to improve data exchange by providing consistent security, performance, scalability, and structure to all users.

Given the progress of such emerging health IT innovation standards to promote interoperability at large, we see increased adoption of approaches utilizing the latest HL7® FHIR® standard as an opportunity to consider how these approaches can support other program goals.

In the CY 2021 PFS final rule, we finalized alignment of the CEHRT definition for the Promoting Interoperability programs with updates to 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule. As part of the ONC 21st Century Cures Act final rule, ONC finalized a new certification criterion ''Standardized API for patient and population services'' at 45 CFR 170.315(g)(10) which supports the availability in certified health IT of an API using the FHIR® R4 standard and other implementation specifications. We noted that technology certified to this criterion will be used to support the API requirements in the Provide Patients Access to their Health Information objective. Regarding the bi-directional HIE measure finalized for eligible clinicians in the 2021 PFS final rule (85 FR 84888 through 84893) (this rule is proposing a similar measure for adoption in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs), we also noted that the standards-based API criterion at 45 CFR 170.315(g)(10) could be used to support connections to an HIE in order to complete the measure's actions.

We are seeking comments on our intention to further align Medicare Promoting Interoperability Program measures with approaches utilizing HL7® FHIR® standard Release 4-based API functionality (or the appropriately evolved standard), with the Health Information Exchange as well as the Public Health and Clinical Data Exchange objectives. Throughout this ongoing developmental process, we are partnering with ONC and continuing to strengthen collaboration on the implementation of the ONC 21st Century Cures Act final rule.

We are interested in public comments on how these two program objectives could be furthered through the use of FHIR®-based API solutions. Specifically, we are interested in the following questions:

- To what degree are stakeholders currently using or interested in using APIs to exchange information in support of the numerator/denominator measures under the HIE objective? What revisions to the measures under the HIE objective should CMS explore to facilitate use of standards-based APIs in health IT modules certified under the 2015 Edition Cures Update?
- How could technical approaches utilizing the FHIR® standard enhance existing data flows required under the public health measures? What are promising FHIR-based approaches to public health reporting use cases that ONC and CMS should explore for potential future consideration as part of the Promoting Interoperability program and the ONC Health IT Certification Program?
- To what degree are PHAs and individual states currently exploring API-based approaches to conducting public health registry reporting? What other factors do stakeholders see as critical factors to adopting FHIR®-based approaches?
- What potential policy and program changes in CMS and other HHS programs could reduce health care provider and health IT developer burden related to measures under the Health Information Exchange and the Public Health and Clinical Data Exchange objectives?

b. Request for Information on a Patient Access Outcomes Measures

The evolution of EHRs has created a greater and more seamless flow of information within a digital healthcare infrastructure, which allows for comprehensive records to be made available wherever and whenever they are needed in the clinical setting. These advances have led to: (1) Improved patient care; (2) increased patient participation; (3) improved care coordination; (4) greater practice efficiencies and cost savings; and (5) improved diagnostics and patient outcomes.[1445] Much research has been dedicated to looking at the implementation of health IT in practice settings with its wide array of potential benefits, but equally important is better understanding the patient's role as an active end-user as well.

Several large, nationally representative surveys have been completed annually in order to collect and evaluate the public's access and use of health information. One of these endeavors operated by the National Cancer Institute (with support from ONC) is called The Health Information National Trends Survey (HINTS) that produces a plethora of key utilization data specifically pertaining to consumers' access and use of their online medical records via patient portals. The HINTS results point to an overall year-over-year rise in the number of Americans who are not only accessing their medical records online (from 51% in 2018 to 58% in 2019 [1446]) but are increasingly doing so to perform meaningful actions such as to view lab test results, transmit their data to a third-party, and to securely message their health care provider. While sources like the HINTS survey are revealing preferential trends, habits, and other key utilization points, the data also show some strong barriers associated with patients accessing EHR technology and continue to stress the need for further work in understanding these users' access outcomes.

We believe a strong partnership between EHR vendors, health care providers, and beneficiary users' outcomes is critical to improving the future of health care and furthering interoperability. Therefore, we are seeking comments surrounding changes to the Medicare Promoting Interoperability Program and related efforts which could better target patient access outcomes related to use of patient portals or third-party application(s). This request for information is an opportunity to garner general interest, solicit stakeholder feedback on how to best evaluate issues of patient behavior, and to explore additional key outcome variables to capture for measurement.

Specifically, we are looking for feedback on the following questions:

- What do stakeholders believe would be useful ways to measure patients' access to their electronic health information using health IT methods such as patient portals and/or third-party applications? What actionable figures related to users' medical record behavior, including but not limited to, the frequency of logins, number of messages sent, or lab results viewed could be captured?
- How effectively is the Medicare Promoting Interoperability Program currently measuring the use of health IT-enabled processes to improve patient outcomes? What measures in the current program are most relevant to patient outcomes?
- Should we consider requiring providers to maintain a record of third-party applications which patients have used to access their patient health information through APIs incorporated within certified technology so that this information could be used to assess patient usage of these applications?
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Medicare Promoting Interoperability Program) that can increase patient utilization of tools to access their health information? How do these technologies and features support improved access or usability within EHR systems and other applications (for instance, alternate authentication technologies that can simplify consumer logon)? How could

[1445] *https://www.healthit.gov/topic/health-it-basics/benefits-ehrs.*

[1446] Patel, V. Johnson, C. (2020). *The Current State of Patients' Access and Use of their Electronic Health Information* [PowerPoint presentation]. The Office of the National Coordinator for Health Information Technology Annual Meeting.

CMS reward health care providers for higher adoption rates and use of these available technologies?

- What are key administrative processes that could benefit from more efficient electronic workflows? How could CMS measure and reward participating eligible hospitals or CAHs for either greater uptake of patient portal access or subsequent health outcomes?

c. Request for Information on Clinical Notes

OpenNotes is an international movement aimed to spread and study the effects of transparent communication among patients, families, and clinicians.[1447] With more than 50 million patients in the U.S. and Canada having gained access to their clinical notes, the push for patient engagement and transparent communication continues to grow.[1448] ''Clinical notes'' are regarded as highly desirable data necessary for the interoperable exchange of health information and patient access. Comprised of structured and unstructured data, clinical notes may include the assessment, diagnosis, plan of care and evaluation of plan, patient teaching, and other relevant data.

While the ability to share clinical notes has been previously supported for certified health IT in different ways, ONC took additional steps to ensure this important patient information is available as part of the recent ONC 21st Century Cures Act final rule (85 FR 25674 through 25677). In the rule, ONC finalized eight types of ''clinical notes'' required under the USCDI version 1: (1) Discharge Summary Note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedure Note.[1449]

As previously discussed in the CY 2021 PFS final rule (85 FR 84825), we finalized to align the CEHRT definition under the Medicare Promoting Interoperability Program with the updates to certification criteria finalized under the ONC 21st Century Cures Act final rule. This alignment includes updates to several certification criteria to refer to the USCDI and the expanded support for clinical notes specified in the USCDI version 1 standard. New and updated certification criteria incorporating the USCDI, include the ''view, download, and transmit'' criterion at 45 CFR 170.315(e)(1), and the ''Standardized API for patient and population services'' criterion at 45 CFR 170.315(g)(10). Once health IT developers and providers have completed implementation of these updates, certified health IT utilized for participation in the Promoting Interoperability Programs will support availability of the clinical note types in the USCDI as part of the data set made available to patients under the Provide Patients Access to their Health Information measure. According to the policy finalized in the CY 2021 PFS final rule, eligible hospitals and CAHs may begin using updated technology as soon as it is available from their developers (effective upon the effective date of the CY 2021 PFS final rule), with updated technology being required for reporting periods beginning in CY 2023.

Under this RFI, we are seeking feedback on changes we can make that will better support the goals of the OpenNotes movement to ensure that clinical notes are widely available to patients. Given the implementation of updates to certified technology, as previously described, that support the Provide Patients Access to their Health Information measure, are there additional changes to this measure, or other program guidance, which could further facilitate ensuring clinical notes are available to patients consistent with the goals of the OpenNotes movement? We are also seeking stakeholder feedback on the development of a required and independently scored measure for the Medicare Promoting Interoperability Program to allocate points for the use of ''clinical note'' types supported by certified health IT. Finally, we are seeking comment on the types of clinical notes that are commonly sought, but not easily accessible to patients.

d. Request for Information on Designating High Performing Hospitals

Several industry-sponsored models have been developed to recognize and distinguish hospitals and CAHs for their adoption and utilization of EHR functionality. Scored and ranked, these designations have been developed by industry experts to highlight key areas such as level of EHR adoption, comparative capabilities to rank hospitals, and serving as a marketing tool for public recognition. Two examples include the HIMSS Analytics Electronic Medical Record Adoption Model (EMRAM)[1450], and the CHIME Most Wired Model[1451]. EMRAM is an eight-stage model scoring hospitals relative to their Electronic Medical Records (EMR) capabilities, measuring the adoption and utilization of EMR functionality. The Most Wired is a ten-stage model, which encourages maximizing the use of information technology to improve patient safety and outcomes, while forging change in health IT.

We are seeking stakeholder feedback on the development of, or support and adoption of, designating high performing hospitals in the context of EHR excellence. Specifically, we seek stakeholder input on the following questions:

- Are there specific industry-based models that are wholly representative of EHR excellence in the hospital or CAH setting? Which model is most representative and why?
- What are the limitations in applying for, or receiving one of the industry-based designations? What would help facilitate hospitals and CAHs to obtain and maintain such a designation?
- Does earning a designation accurately reflect EHR excellence within the patient community or amongst hospitals and CAHs?
- Is there interest in a CMS-driven designation program? If so, which components are most meaningful and valuable to hospitals and CAHs?
- We would like feedback on the potential of developing a Star Rating for Promoting Interoperability, or, adding Promoting Interoperability as a category for existing Star Ratings. Would this effort accurately represent EHR excellence?

X. Other Policy Provisions

A. Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost-Sharing for Services Furnished to Dually Eligible Beneficiaries

1. Background

Dually eligible beneficiaries are those enrolled in both Medicare (either Part A, Part B, or both) and Medicaid. About 8 million dually eligible individuals are enrolled in the Qualified Medicare Beneficiary (QMB) program,[1452] which is a Medicaid benefit that assists low-income Medicare beneficiaries with Medicare Part A and Part B premiums

[1447] *https://www.opennotes.org/about/.*

[1448] *https://www.opennotes.org/history/.*

[1449] *https://www.healthit.gov/isa/uscdi-data/clinical-notes#uscdi-v1.*

[1450] *https://www.himssanalytics.org/emram.*

[1451] *https://chimecentral.org/chime-most-wired-2/#tab_ert_pane1-0.*

[1452] Under 1905(p)(1) of the Act, a QMB is an individual who is entitled to hospital insurance benefits under Part A of Medicare, with income not exceeding 100 percent of the Federal poverty level, and resources not exceeding three times the SSI limit, adjusted annually by the Consumer Price Index. For more information about QMB eligibility and benefits, see chapter 1, section 1.6.2.1 and Appendices 1.A and 1.B of the Manual for the State Payment of Medicare Premiums.

and cost sharing. QMB ''Medicare cost-sharing'' amounts, as defined in section 1905(p)(3) of the Act,[1453] include Medicare Part A and B premiums, coinsurance, and deductibles. Section 1902(a)(10)(E) of the Act directs states to pay providers for Medicare coinsurance and deductibles. Under section 1905(p)(3) of the Act, ''Medicare cost-sharing'' includes costs incurred with respect to a QMB, regardless of whether the costs incurred were for items and services covered under the Medicaid State plan. Additionally, some State Medicaid agencies also elect to pay the Medicare cost-sharing for other (non-QMB) dually eligible beneficiaries.

However, section 1902(n)(2) of the Act permits the State to limit payment for Medicare cost-sharing to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid State plan payments, and third party payments) equal to the amount a State would have paid for the service under the Medicaid State plan. This is often referred to as the ''lesser-of'' policy.

If a State has adjudicated its Medicare cost-sharing to a provider pursuant to the lesser-of policy for an individual enrolled in the QMB program, section 1902(n)(3) of the Act prohibits the provider from collecting the remaining amount from the beneficiary.[1454] However, certain providers may recover a portion of these unpaid cost-sharing amounts as Medicare ''bad debt'' if they meet all the requirements in 42 CFR 413.89 and as described further in the Provider Reimbursement Manual Part 1 Chapter 3. Pursuant to § 413.89(h), bad debt payments are generally 65 percent of the uncollected amount for these services.

Per 42 CFR 413.89, providers must exclude any cost-sharing amount legally owed by the State from Medicare bad debt amounts claimed. CMS requires a provider that furnishes services to a dually eligible beneficiary to determine whether the State's Medicaid program (or applicable third party) is responsible for paying all or a portion of the beneficiary's Medicare deductible and/or coinsurance (and if so, how much) before the provider can claim these amounts as Medicare bad debt. Before claiming any unpaid cost-sharing amounts as a Medicare bad debt for a dually eligible beneficiary, the provider must bill the State or State designee, such as a Medicaid managed care organization (MCO) (the ''must bill'' policy), and obtain from the State or State designee documentation of completed claim processing and claim adjudication information in the form of a Medicaid remittance advice (RA) [1455] that sets forth the State's cost-sharing liability for the items and services the beneficiary received (the ''RA'' policy).

2. Claims for Medicare Cost-Sharing for Dually Eligible Beneficiaries and Misaligned Medicare and Medicaid Provider Enrollment

Section 1903(a)(3)(A)(i) of the Act requires each State Medicaid Management Information System (MMIS) to process Medicare claims for dually eligible beneficiaries for Medicare cost-sharing. Furthermore, to comply with sections 1902(a)(10)(E) and 1902(n)(1) and (2) of the Act, the State MMIS must be able to process all such claims for Medicare cost-sharing liability even if the Medicaid State plan does not recognize a service or provider category.[1456] Nevertheless, some states in the past have inhibited enrollment of certain types of providers or suppliers that are not explicitly included in their State plan. If a Medicare-enrolled provider or supplier has been unable to enroll with the State Medicaid program, then the State MMIS may not adjudicate the cost-sharing claim and also may not return a Medicaid RA to the provider for the purposes of computing Medicare bad debt absent further actions by the State or by the provider.

To clarify states' obligations regarding claims for Medicare cost-sharing by adding a new paragraph (d) to 42 CFR 455.410 to clearly specify in regulation *how* states must meet this obligation. Specifically, we propose that, for purposes of determining Medicare cost-sharing obligations, the State Medicaid programs must accept enrollment of all Medicare-enrolled providers and suppliers (even if a provider or supplier is of a type not recognized as eligible to enroll in the State Medicaid program) if the provider or supplier otherwise meets all Federal Medicaid enrollment requirements. These Federal requirements include, but are not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. States must process claims from such providers requesting that the State determine its cost-sharing liability. States are already directed to issue RAs under section 11325.A of the State Medicaid Manual (stating that the Medicaid MMIS must produce remittance advice to providers) as part of its responsibility, already required pursuant to 42 CFR 433.112(b)(3), to process claims for dual eligible beneficiaries. We note that neither this existing guidance nor the provisions of this proposed rule would require states to recognize or enroll additional provider types for purposes other than submission, adjudication of cost-sharing claims, and issuance of a Medicaid RA. Accordingly, states may wish to consider a separate enrollment process or provider enrollment category specifically for Medicare providers and suppliers for purposes of determining cost-sharing, consistent with existing law, acknowledging that individual states are in the best position to assess the feasibility of this or other possible approaches. We leave it to states to determine how best to implement these requirements consistent with their system needs and capabilities, provisions of their Medicaid State plan and State law, and Federal Medicaid provider enrollment regulations and sub-regulatory guidance.[1457] However, states should consult with CMS to help ensure their compliance with 42 CFR 455.410(d) and other Federal provider enrollment requirements related to this proposal.

We propose that State Medicaid programs and their applicable systems be in compliance with proposed § 455.410(d) in time to process cost-sharing claims for dually eligible beneficiaries with dates of service beginning January 1, 2023, recognizing that, despite current MMIS requirements, some states may need to make systems changes to comply. Updates to the State MMIS are likely eligible for 90/10 Federal medical assistance percentage (FMAP) as set forth in 1903(a)(3)(A) of the Act. If necessary, we will propose specific enforcement penalties for non-compliance in future rule making. We

[1453] A State's requirement to determine its cost-sharing liability for QMBs is also set forth at section 3490.14(A) of the State Medicaid Manual (SMM) (CMS Pub. 45).

[1454] Medicare providers who violate these billing prohibitions are violating their Medicare Provider Agreement and may be subject to sanctions (see sections 1902(n)(3), 1905(p), 1866(a)(1)(A), and 1848(g)(3) of the Act).

[1455] The FY 2021 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System final rule (85 FR 58432), published on October 1, 2020, created the Medicaid RA alternative documentation policy with a retroactive effective date, to allow providers with pending appeals a way to submit alternative documentation to the Medicaid RA that sets forth the state's liability for the cost-sharing. We anticipate the alternative documentation policy will only need to be in effect until states comply with the existing statute and process crossover cost-sharing claims for all Medicare providers. We would consider in future rulemaking removing the alternative once states comply with our proposal in this notice of proposed rulemaking.

[1456] *https://www.medicaid.gov/Federal-policy-guidance/downloads/cib-06-07-2013.pdf.*

[1457] Medicaid Provider Enrollment Compendium (MPEC).

discuss Medicaid burden associated with these system changes in section I.H.10 of Appendix A of this proposed rule.

We believe that the requirements of proposed § 455.410(d) may reduce the number of future bad debt appeals by ensuring certain Medicare-enrolled providers and suppliers can enroll with State Medicaid programs, receive Medicaid Remittance Advice (RAs), and claim Medicare bad debt. In reducing these appeals, the proposal would reduce the cost for providers to pursue such appeals and subsequent litigation, as well as the costs for CMS to defend them. Therefore, we estimate provider and Federal savings from avoiding future Medicare bad debt appeals. We discuss this reduction in provider and Federal burden in detail in section I.H.10 of Appendix A of this proposed rule.

Failure of State MMIS to provide an RA for cost-sharing claims for dually eligible beneficiaries may also contribute to reduced access to care. Some providers may choose not to treat, or continue treating, dually eligible beneficiaries, due to the provider burden associated with getting paid for cost-sharing claims; a decrease in providers willing to serve the dually eligible population could result in fewer health care options for beneficiaries. We believe this proposal may have a positive impact on beneficiary access to care through reduced provider burden.

In addition to certain Medicare-recognized provider and supplier types having difficulty enrolling in some Medicaid programs for purposes of submitting cost-sharing claims, as previously discussed, we have also heard that some providers have had difficulty getting states to process certain cost-sharing claims for services that are not payable by the State under the terms of the Medicaid State Plan. We received feedback from providers that some states determine their cost-sharing liability for a Medicare service by applying the Medicaid payment and coverage rules for the service as if the service (rather than the cost-sharing) were being paid by Medicaid. This means that the State MMIS will reject, deny, or return zero liability for a claim for Medicare cost-sharing unless the provider completes Medicaid documentation and meets Medicaid coverage and payment standards. For example, a provider submits a claim for oxygen therapy for use in home with a lifetime length of need and the claim meets Medicare payment and coverage standards.[1458] When the provider submits this claim for Medicaid payment of cost-sharing (or when Medicare ''crosses over'' the claim to the State), the State denies the claim because the claim does not meet the State's conditions of Medicaid payment for oxygen therapy (that is, the provider must complete and sign a State's Medicaid certificate of medical necessity or certificate of need, which requires different Medicaid coding and modifiers, and has a maximum length of need of 12 months). A State operational policy like this creates unnecessary work for providers, suppliers, and beneficiaries. It could also prevent the State from meeting its actual cost-sharing liability. Building on the provider enrollment requirement in proposed § 455.410(d), we considered proposing a policy that states must process claims for Medicare cost-sharing without requiring that the claim meet the Medicaid State plan coverage and payment rules for that service. Instead, we request additional feedback from stakeholders on the scope of this practice, including State and service specific examples, and we will consider whether to include such a policy or otherwise address the issue in future rulemaking.

B. Organ Acquisition Payment Policies

1. Background

a. History of Medicare Organ Acquisition Policies

The Medicare Program supports organ transplantation by providing an equitable means of payment for the variety of organ acquisition services. Medicare excludes organ acquisition costs from the inpatient hospital prospective diagnosis-related group (DRG) payment for an organ transplant, and separately reimburses transplant hospitals [1459] (THs) for the organ acquisition costs on a reasonable cost basis (42 CFR. 412.2(e)(4) and 412.113(d)).[1460]

Medicare's current organ acquisition policy is modeled after the kidney acquisition policy that was implemented for kidney transplants following the Social Security Amendments of 1972 (Pub. L. 92–603) that extended Medicare coverage to individuals with end stage renal disease (ESRD) who required dialysis or transplantation. In July 1973, CMS (then the Bureau of Health Insurance [1461] (BHI)) issued Intermediary Letters (ILs) which set forth procedures and policies for Medicare reimbursement for kidney transplants. The IL 73–25 (July 1, 1973) set forth policies for the reimbursement for kidney transplants and dialysis, including policies for hospital reimbursement for the acquisition of a kidney from cadaveric and living donors for transplant into a Medicare beneficiary. In IL 73–25, the BHI commented that as it received and analyzed data and studied reimbursement methodology, it would develop and issue more detailed reimbursement instructions to support the delivery of quality services in an efficient manner. In July 1974, the BHI issued IL 74–23, which set forth additional policies for Medicare reimbursement of kidney acquisition costs, many of which remain in place currently. In 1978, to clarify that the Secretary of the Department of Health and Human Services (the Secretary) has authority and to provide reimbursement for the costs incurred in connection with kidney donations, Congress enacted legislation that added special provisions relating to coverage under the Medicare Program for ESRD (Pub.L. 95–292). This legislation added section 1881 to the Act that set forth Medicare payment for kidney transplantation and the coverage of organ procurement costs and living donor expenses, including Part A and Part B benefits for the living donor.[1462] As CMS stated in the 1978 **Federal Register** (43 FR 44803), the purpose of section 1881 of the Act was to encourage kidney transplantation and the scope of Medicare benefits to cover all reasonable preparatory, operation and post-operation expenses associated with a kidney donor, through the actual period of recovery.

Over the years through various rulings and national coverage determinations, Medicare has added coverage for transplantation of non-renal organs such as heart, liver or lungs; we modeled our reimbursement for the acquisition costs for non-renal organs based on our earlier

[1458] We note that any remaining unpaid deductible and coinsurance amounts associated with oxygen and oxygen equipment paid under a Medicare fee schedule cannot be an allowable Medicare bad debt.

[1459] Under 42 CFR 482.70 a transplant hospital is a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

[1460] Pursuant to 42 CFR 412.113(d), organ acquisition costs incurred by hospitals with approved transplant programs are paid for on a reasonable cost basis.

[1461] To implement the Medicare statute, the Social Security Administration was reorganized and the Bureau of Health Insurance (BHI) was established on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed the Centers for Medicare & Medicaid (CMS). CMS Milestones 1937–2015 (July 2015).

[1462] H. Rep. 95–549 (July 29, 1977), section III.B.; S. Report 95–714 (Mar. 22, 1978), section III.B.

kidney acquisition policies. Medicare's organ acquisition payment policy is mostly set forth in CMS Pub. 15–1, chapter 31,[1463] the Provider Reimbursement Manual (herein referred to as PRM) and in Medicare regulations at 42 CFR 412.2(e)(4), 412.100, 412.113(d), 413.200, 413.202, and 413.203. The entities involved in organ acquisition, which we will further define and discuss herein, are THs, donor community hospitals (Medicare-certified non-transplant hospitals), organ procurement organizations (OPOs), some of which are hospital-based OPOs (HOPOs), and histocompatibility laboratories.

Section 1102 of the Act authorizes the Secretary to publish rules and regulations necessary for the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871(a) of the Act authorizes the Secretary to prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title. In this proposed rule, we are proposing to codify into the Medicare regulations some longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and proposing to codify some new organ acquisition payment policies. We are also proposing to move existing organ acquisition payment regulations or portions of existing kidney acquisition regulations within title 42 of the CFR part 412, subpart G and Part 413, subpart H to a new proposed Part 413, subpart L, so that all organ acquisition payment policies are housed together. We are also proposing to codify into new subpart L certain policies pertaining to organ acquisition, as set forth in section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) and section 17006 of the 21st Century Cures Act (Pub. L. 114–255), pursuant to their statutory effective dates. We are also proposing to make conforming changes and technical corrections to the regulations, where necessary.

We are aware of OIG audits reporting that some OPOs have billed the Medicare Program for unallowable expenditures.[1464] There have also been recent Congressional oversight interest and inquiries into OPO financial management.[1465] We believe the proposals that follow would provide clarity and allow providers and stakeholders to more easily locate and understand organ acquisition payment policy, resulting in more accurate payment based on reasonable cost principles. We look forward to considering public comments on this proposed rule.

b. Overview of Medicare Reimbursement in Transplantation

Medicare reimburses THs for organ acquisition costs, the transplant surgery, inpatient, and post-transplant costs for the Medicare recipients, but through different payment systems. Medicare Part A pays for hospital costs of a transplant surgery and certain follow-up care through a DRG payment and the organ acquisition costs associated with a transplant on a reasonable cost basis. In general, Medicare Part B pays for the physician services and other services furnished to eligible Medicare beneficiaries. CMS established Conditions of Participation (CoP) for hospitals under 42 CFR part 482, subpart E. Transplant programs, located within a TH that has a Medicare provider agreement, must meet the hospital CoPs at §§ 482.1 through 482.70 and the transplant program CoPs, located at §§ 482.72 through 482.104, and additional requirements in order to be eligible to participate in the Medicare Program.

OPOs coordinate the procurement, preservation and transportation of organs from deceased donors, and maintain a system for locating prospective recipients for organ transplantation. Section 1138 of the Act sets forth hospital protocols for the identification of potential organ donors and the standards for OPOs. To be an OPO, an entity must meet the applicable requirements of both the Act and the Public Health Service Act (the PHS Act). The statutory functions of an OPO are also set forth in 42 U.S.C. 273; section 371 of the PHS Act. Section 1138(b) of the Act provides the statutory qualifications and requirements that an OPO must meet in order to be reimbursed under the Medicare or Medicaid Program for certain organ procurement costs. CMS established Conditions for Coverage (CfCs) OPOs must meet in order to receive payment under Medicare or Medicaid for organ procurement costs in the regulations at 42 CFR part 486, subpart G. Section 1138(b)(1)(A) of the Act specifies that payment may be made for organ procurement costs only if the agency is a qualified OPO operating under a grant made under section 371(a) of the PHS Act or has been certified or re-certified by the Secretary as meeting the standards to be a qualified OPO. Among those requirements, each OPO must be a member of, participate in, and abide by the rules and requirements of the Organ Procurement Transplantation Network (OPTN) that are approved by the Secretary. (See 42 CFR 486.320.)

Medicare reimburses THs for organ acquisition costs under reasonable cost principles[1466] pursuant to section 1861(v) of the Act, based on the TH's ratio of Medicare usable organs to total usable organs. Medicare authorizes payment to designated OPOs for kidney acquisition costs, under reasonable cost principles[1467] pursuant to section 1861(v) of the Act, based on the OPO's ratio of Medicare usable kidneys to total usable kidneys (see section 1881(b)(2)(A) of the Act).

Histocompatibility laboratories provide laboratory services to ensure compatibility between donor organs and potential recipients in preparation for transplants. Section 1881(b)(2)(A) of the Act authorizes Medicare reimbursement for the cost incurred by a histocompatibility laboratory pursuant to sections 1861(v) or 1886 (if applicable). Histocompatibility laboratories are either independent or hospital-based. A histocompatibility laboratory is ''independent'' unless it is considered a department of the hospital and subject to control of the hospital.[1468] 42 CFR 413.200(a) requires the reasonable costs of services furnished by histocompatibility laboratories be reimbursed in accordance with the principles contained in 42 CFR 413.60 and 413.64.

2. Organ Acquisition Payment Policy Proposals

a. Terminology Notes and Proposed Definitions

(1) Use of Consistent Terminology

Throughout this proposed rule, we will use consistent terminology such as ''transplant hospital'' and ''transplant program.'' These terms have been

[1463] CMS Pub. 15–1, chapter 31 can be found at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*) (Prior to the creation of chapter 31, the kidney acquisition policy was set forth in CMS Pub. 15–1, chapter 27, Outpatient Maintenance Dialysis Reimbursement).

[1464] *https://oig.hhs.gov/oas/reports/region9/90800033.pdf*; *https://oig.hhs.gov/oas/reports/region9/90900087.pdf*; *https://oig.hhs.gov/oas/reports/region9/90500034A.pdf*; *https://oig.hhs.gov/oas/reports/region9/91102039.pdf.*

[1465] *https://oversight.house.gov/news/press-releases/oversight-subcommittee-launches-investigation-into-poor-performance-waste-and* ; *https://www.young.senate.gov/newsroom/press-releases/young-joins-finance-committee-members-to-probe-us-organ-transplant-system.*

[1466] See 42 CFR 412.113(d); HCFA Ruling 87–1 (April 1987); CMS Ruling 1543–R (December 2006).

[1467] Id. Section 1138(b)(1)(F) of the SSA; 42 CFR 413.1(a)(1)(ii)(A); 413.200(a).

[1468] 43 FR 58371 (December 14, 1978).

defined in other CMS regulations at 42 CFR 482.70 as:

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

The regulations in 42 CFR parts 412 and 413 had previously used ''transplantation center'' to mean a ''transplant program.'' Our PRM also uses ''certified transplant center'' to mean a TH, but we are proposing to use consistent language in this rule to avoid confusion. Thus, throughout this proposed rule, we will refer to a hospital that has an approved organ-specific transplant program as a TH, and we will use ''transplant program'' to refer to the organ-specific program itself. In section X.B.2.m.(1) of this proposed rule, we are proposing conforming changes to some existing regulations to ensure that ''transplant hospital'' and ''transplant program'' are used consistently and as described here.

(2) Proposed Definitions

In addition to using consistent terminology throughout this rule, we are proposing to add specific definitions into the regulations by adding § 413.400, entitled ''Definitions,'' to new subpart L of 42 CFR, part 413. We are also proposing to move all definitions in existing § 413.200(b) ''*Definitions,*'' to new § 413.400 to maintain this regulation with all other organ acquisition regulations in proposed new subpart L of part 413. Further, we are proposing to revise some of the definitions proposed to be moved from § 413.200(b) to new § 413.400, as noted in the following discussion.

For organ acquisition payment purposes, an ''organ,'' means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine) as defined in 42 CFR 486.302. Effective October 1, 2004, organs also include pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial. We are proposing to codify our proposed definition for ''organ'' in § 413.400, new subpart L.

Medicare makes payment for such pancreata in accordance with section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173) which requires Medicare to pay for items and services that are reasonable and necessary routine patient care costs related to acquisition and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries included in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplants.

Our proposed definition of organ is for Medicare organ acquisition payment purposes and differs from the definition set forth in 42 CFR 486.302 CfC for OPOs. The CMS OPO CfCs final rule (85 FR 77947 published December 2, 2020), defines ''organ'' under 42 CFR 486.302, to mean a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine). The pancreas counts as an organ even if it is used for research or islet cell transplantation. The final rule describes the inclusion in the performance measures for OPO certification of pancreata used for research in the definition of organ as necessary in order to meet the statutory requirements of section 371(c) of the Public Health Service Act that provides pancreata procured by an OPO and used for islet cell transplantation or research shall be counted for purposes of certification or recertification (85 FR 77902). However, for Medicare payment purposes, an organ procured for research is not counted as a Medicare organ in Medicare's share of organ acquisition costs, except where explicitly required by law. Therefore, in order to mitigate potential stakeholder confusion, we are proposing a definition of ''organ'' for organ acquisition payment purposes that differs from the definition set forth in the OPO CfCs.

We are proposing to include the definition of Organ Procurement Organization (OPO) as it currently exists in § 413.200(b). As defined in 42 CFR 486.302, an OPO means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs. An OPO can be a HOPO or an independent OPO. An OPO is ''independent'' unless it is considered a department of the hospital and subject to control of the hospital.

Additionally, we are proposing to codify the definition of a HOPO as an OPO that is considered a department of the TH and reports organ acquisition costs it incurs on the TH's Medicare cost report (MCR).[1469] The proposed definition is consistent with the description of HOPO in the PRM, and is commonly known in the organ acquisition and transplant community. We are proposing to codify our proposed definition in § 413.400, new subpart L. As of March 12, 2021, there are 7 HOPOs in operation.[1470]

We are also proposing that a *transplant hospital/HOPO (TH/HOPO)* refers to a transplant hospital, or a transplant hospital that operates a HOPO (as defined previously in this section) and performs organ procurement activities as one entity reported on the transplant hospital's MCR. We are proposing to codify our proposed definition in § 413.400 new subpart L.

We are also proposing to revise the terminology ''freestanding'' as it currently exists in 42 CFR 413.200(b) in relation to OPOs, to be ''independent OPO (IOPO)'' because this terminology is more widely used in the industry. We are also proposing to revise the IOPO definition by adding a third distinguishing factor. The proposed definition for an IOPO would mean an OPO that files a MCR separate from a hospital and meets all of the following: (1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees; (2) is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance); and (3) reports organ acquisition costs it incurs on the IOPO MCR.[1471] We are clarifying that an IOPO that wishes to have the cost of its pre-transplant services reimbursed under Medicare must agree to certain requirements specified in 42 CFR 413.200(c). If an IOPO operates a histocompatibility laboratory, the costs of its histocompatibility laboratory are included on the IOPO's MCR. We are proposing to codify our proposed definition in § 413.400, new subpart L.

A histocompatibility laboratory performs laboratory services to determine the degree of histocompatibility between donor organs and potential recipients. We are also proposing to include a definition of ''histocompatibility laboratory'' as it currently exists in § 413.200(b) with a technical correction. We are proposing to make a technical correction to the cross-reference to § 413.2171(d) because

[1469] Hospital and Health Care Complex Cost Report, currently Form CMS–2552, OMB No. 0938–0050.

[1470] Information available at *https://optn.transplant.hrsa.gov/members/*; accessed March 12, 2021.

[1471] Organ Procurement Organizations and Histocompatibility Laboratory, currently Form CMS–216, OMB. No. 0938–0102.

this regulation citation is no longer correct. We are proposing that ''histocompatibility laboratory'' means a laboratory meeting the requirements set forth in 42 CFR 493.1227 and providing the services for the acquisition of kidneys or other organs for transplantation. We are proposing to codify our proposed definition in § 413.400, new subpart L.

We are proposing that standard acquisition charge (SAC) means a charge as defined in proposed new § 413.404 in section X.B.2.c. of this proposed rule. We are proposing to codify our proposed definition in § 413.400, new subpart L.

We are also proposing to add the definitions for ''transplant hospital'' and ''transplant program'' that currently exist in 42 CFR 482.70 in § 413.400, to new subpart L.

b. Proposals Related to Organ Acquisition Costs

(1) Proposed Items and Services Considered Organ Acquisition Costs

In this proposed rule, we are proposing to add § 413.402(a) to new subpart L to specify that costs incurred in the acquisition of organs from a living donor or a cadaveric donor by the hospital or by an OPO, as appropriate, are organ acquisition costs. To make necessary policy revisions and clarifications of acquisition costs for kidneys as well as for non-renal organs, we are proposing to revise § 412.100(b), by removing the list of organ acquisition costs found in that paragraph and re-codifying them with some revisions by adding § 413.402(b) to new subpart L.

We are proposing to codify that the costs of acquiring organs (kidneys and non-renal organs) covered by Medicare Part A are: (1) Tissue typing, including tissue typing furnished by independent laboratories; (2) donor and beneficiary evaluation; (3) other costs associated with excising organs, such as general routine and special care services provided to the donor; (4) operating room and other inpatient ancillary services applicable to the donor; (5) preservation and perfusion costs; (6) OPTN registration fees; (7) surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys); (8) transportation of the excised organ to the TH; (9) costs of organs acquired from other hospitals or OPOs; (10) hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to admission); (11) costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs; and (12) all pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and surgeons' fees for cadaveric excisions, applicable to organ excisions including the costs of physicians' services.

We are proposing to apply the existing elements of kidney acquisition costs found in § 412.100(b) to all organs, with clarifying revisions as described here. These items and services are currently specified in § 412.100(b) (for kidneys only) and also discussed in sections 3101, 3102, and 3103 of the PRM. We are proposing to revise § 412.100(b) to reference that kidney acquisition costs are specified in new § 413.402(b) of this chapter.

We are proposing to add § 413.402(b) to new subpart L to include the costs for registration of a beneficiary for a kidney transplant as specified in § 412.100(b)(6) and also include the costs for registration of a beneficiary for a non-renal transplant. The OPTN registration fee is assessed for all transplant candidates placed on the OPTN waiting list.[1472] We are proposing to limit these registration fees to the OPTN registration fee. Reasonable cost principles, as set forth in section 1861(v) of the Act and specified in 42 CFR 413.1(b) and § 413.9, do not permit Medicare to pay for duplicate services. Any registration fee outside of the OPTN registration fee would be considered unnecessary and duplicative under reasonable cost principles for Medicare organ acquisition costs.

Some kidney acquisition costs differ depending on whether the donor is living or is cadaveric. Our proposal would codify that surgeon fees are included as kidney acquisition costs only when the kidney excision occurs with a cadaveric donor. When a living donor enters the hospital for the actual kidney excision, surgeon fees for excising the kidney are not included as kidney acquisition costs. The surgeon bills these surgeon fees to Medicare Part B using the transplant recipient's Medicare Beneficiary Identifier (MBI). Congress enacted section 1881(d) in 1978, which (in part) entitled living donors to benefits under Medicare Part B with respect to the kidney donation, as if the donor were eligible for Medicare, and allowed the Secretary to prescribe in regulation how that would occur. CMS (then HCFA) implemented regulations at 42 CFR 405.231 and 405.244–1,[1473] (which were subsequently relocated to 42 CFR 410.55 and 410.163),[1474] which required Medicare Part B to pay for medical and other health services furnished in connection with a kidney donation if the kidney is intended for a Medicare beneficiary with ESRD, regardless of whether the donor is entitled to Medicare, and without deductibles or co-insurance. As such, our proposed codification of Part A kidney acquisition costs related to donor surgeon fees only focuses on surgeons' fees for cadaveric excisions.

Section 371(b)(3)(F) of the PHS Act, 42 U.S.C. 273(b)(3)(F), requires that OPOs provide or arrange for the transportation of donated organs to transplant centers. Our proposal clarifies our longstanding policy in PRM section 3101 that Medicare covers the transportation of donated organs as an organ acquisition cost as authorized by section 371(b)(3)(F) of Public Health Service Act.

We are proposing to add § 413.402(b) to new subpart L to specify the acquisition costs given at § 412.100(b) of this chapter, with minor clarifying revisions, and to revise § 412.100(b) to cross-reference § 413.402(b). We are also proposing to make additional revisions, technical corrections and conforming changes to § 412.100 in sections X.B.2.b.(1) and X.B.2.m.(2) of the preamble of this proposed rule.

Finally, we have received inquiries from various stakeholders about whether costs resulting from services to living kidney donors with complications are organ acquisition costs. We are proposing to codify that policy in § 413.402(c) in new subpart L, to provide greater clarity to stakeholders. We discuss details of our policy and proposed codification related to living kidney donor complications in section X.B.2.e.(4) of this proposed rule.

(2) Cost Reporting, Billing, and Payment of Organ Acquisition Costs

Both THs and OPOs can acquire organs for transplantation; therefore, both THs and OPOs can have organ acquisition costs. A TH can acquire organs from either a cadaveric donor or a living donor, while OPOs acquire organs from cadaveric donors. In accordance with requirements at § 413.24(f), at the end of its fiscal year a TH/HOPO files an annual hospital cost report (currently Form CMS–2552) and an IOPO files an annual OPO/

[1472] The hospital CoPs at 42 CFR 482.45(b)(1) require each TH to be a member of the OPTN and abide by its rules, which for THs include registering potential transplant recipients on the OPTN registry as described in section 1.2.D of the OPTN Bylaws, available at *https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf.*

[1473] 43 FR 49720 to 49723.

[1474] 51 FR 41332.

histocompatibility cost report (currently Form CMS–216). Organ acquisition costs incurred by a TH/HOPO are included on the appropriate organ acquisition cost center on its hospital MCR. Organ acquisition costs incurred by an IOPO (or by a histocompatibility laboratory, as authorized in section 1881(b)(2)(A) of the Act and discussed in section X.B.2.d.(3) of this proposed rule) are included in the appropriate organ acquisition cost center on its MCR.

Currently, Medicare pays THs prospective payment amounts based on a DRG for the actual organ transplant; Medicare also reimburses THs for reasonable and necessary costs associated with acquiring organs for transplantation into Medicare beneficiaries (§ 412.113(d)). CMS excludes from the prospective payment amounts inpatient hospital organ acquisition costs for hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved THs, as specified in § 412.2(e)(4). Medicare makes payment for organ acquisition costs incurred by hospitals with approved transplantation programs on a reasonable cost basis, as specified in § 412.113(d), and in accordance with the principles of reasonable cost as set forth in section 1861(v) of the Act and in 42 CFR 413.1 and 413.9.

When the TH cost report is settled, the Medicare contractor calculates the Medicare organ acquisition costs by multiplying the total of all allowable organ acquisition costs by the ratio of Medicare usable organs to total usable organs, for each organ type. The contractor reconciles the TH's Medicare organ acquisition costs by comparing the total interim payment amounts paid for organ acquisition costs under § 413.64(f) to the total actual Medicare organ acquisition costs, and either pays amounts owed or collects from the TH any overpayment.

The statute at section 1881(b)(2)(A) of Act authorizes Medicare to pay THs for services provided by OPOs for kidney acquisition. Medicare does not directly reimburse OPOs as these services are not covered until the transplant occurs at the TH. At the time of procurement, the OPO does not always know if the organ recipient is a Medicare beneficiary, as the registry database payor information may not be up-to-date. Therefore, OPOs receive an interim payment based on their kidney SAC which is paid directly to them by the TH (or other OPO) that receives the kidney procured. Medicare pays IOPOs for kidney acquisition indirectly, through the reconciliation of actual costs incurred for kidney acquisition to actual kidney SAC payments received, as part of cost report settlement in accordance with § 413.200(e)(2), to ensure that the Medicare Program is paying its appropriate share. There is no explicit statutory requirement for Medicare to pay IOPOs for non-renal organs in the same way, so reconciliation and settlement of IOPO non-renal organ acquisition costs does not occur. Similar to kidney acquisition costs, IOPOs are paid an interim rate (SAC) directly by the TH (or other IOPO) which receives the non-renal organs the IOPO procures. Kidney and non-renal SACs are discussed in more detail in section X.B.2.c of this proposed rule.

(3) Services Not Considered Organ Acquisition Costs

Medicare does not pay for certain costs incurred by OPOs, in accordance with section 1861(v)(1)(A) of the Act, and we are proposing to establish rules identifying those specific items. These activities or services include incurred costs found to be unnecessary in the efficient delivery of health care services, and are not limited to: [1475]

- Burial and funeral expenses for the cadaveric donor, including transportation of the cadaveric donor before and after excision (burials and funerals are not costs of acquiring organs and are not mentioned in section 371(b)(3) of the PHS Act (42 U.S.C. 273(b)(3)), which lists a number of activities or services that OPOs perform; transportation costs are limited to the cost of transporting donated organs to the transplant hospital);
- Costs associated with the transportation of a living or cadaveric donor [1476] (there may be programs outside of Medicare that pay for transportation costs for living donors [1477]);
- Costs incurred prior to a potential donor being declared brain dead (healthcare costs incurred prior to declaration of death are the responsibility of the potential donor's health insurance);
- Fees or in-center payments for donor referrals (all hospitals are required to timely notify OPOs of imminent deaths; [1478] PRM 15–2, chapter 40, section 4013 stipulates that, ''No amounts or fees paid to a donor, their estate, heirs, or assigns in exchange for an organ or for the right to remove or transplant an organ are included in organ acquisition costs.'');
- Costs associated with OPO sponsored seminars where continuing education credits are given [1479] (these costs are not directly associated with acquiring organs); and
- Certain costs incurred for administrator's duties associated with professional organizations (these costs are not directly associated with acquiring organs).

c. Proposals Related to Standard Acquisition Charges

(1) General

In this proposed rule, we are proposing to clarify and codify Medicare's policy regarding TH/HOPO SACs, as set forth in PRM section 3101, and as discussed herein. The IL 74–23, issued in July 1974, set forth the policies and procedures for a hospital to develop standard kidney acquisition charges for the acquisition of kidneys from living or cadaveric donors. Over the years, as Medicare added coverage for non-renal transplants, Medicare used these same policies and procedures for THs to develop living and cadaveric SACs for non-renal organs and OPOs to develop cadaveric SACs for non-renal organs.

A SAC for an organ is an amount that represents the estimated costs a TH or an OPO expects to incur to acquire an organ. The SAC does not represent the actual acquisition cost for an individual organ. Instead, the SAC generally represents the average of the total actual costs associated with procuring either cadaveric donor organs or living donor organs.

A TH or OPO cannot bill Medicare directly for the cost of procuring an organ because procuring an organ is not a covered service when performed independent of a Medicare covered transplant, and it is not always known at the time of organ procurement whether the potential recipient is a Medicare beneficiary. However, the reasonable costs of procuring an organ are reimbursable when billed in connection with a Medicare covered transplant. When a TH bills Medicare for the transplant, it bills the DRG charge for the organ transplant and uses its SAC to bill Medicare for the procured organ (currently using revenue code 081X [1480]). THs develop categories

[1475] PRM 15–1, ch 31, § 3108.C.

[1476] 42 U.S.C. 273(b)(3)(F).

[1477] 85 FR 59438, September 22, 2020; see also the National Living Donor Assistance Center website at *https://www.livingdonorassistance.org/About-Us/Mission-Background*.

[1478] 42 CFR 482.45.

[1479] See CMS Pub. 15–1, chapter 4 for more information regarding allowable costs of educational activities.

[1480] Medicare Internet Only Manual 100–04, Medicare Claims Processing Manual, Chapter 3, Section 90, available at *https://www.cms.gov/*

of living or cadaveric SACs, by organ type (for example, heart, liver or lung). When a TH/HOPO or IOPO provides an organ to another TH or OPO, we are proposing that it must bill the receiving TH, TH/HOPO or IOPO its SAC. We are proposing to codify these provisions pertaining to SACs at proposed new § 413.404(a) in new subpart L.

(2) Transplant Hospitals and HOPOs

In this proposed rule, we are proposing to codify provisions pertaining to SACs for TH/HOPOs for living and cadaveric donors at proposed new § 413.404(b) in new subpart L, as described in this section.

(a) Living Donor Standard Acquisition Charge

In this proposed rule, we are proposing to codify Medicare's longstanding policy regarding a TH's standard acquisition charges for living donors, as set forth in PRM section 3101.A., and as discussed herein, because these policies remain relevant. THs must develop a SAC for living organs, by organ type (for example heart, liver, or lung). THs/HOPOs must develop a SAC for cadaveric organs, by organ type. The living donor SAC is an average cost the transplant hospital incurs to procure an organ from a living donor. As medicine and transplantation have advanced, there now can be transplants from living donors for kidneys, lungs, and portions of livers, pancreata or intestines, and a living SAC can be established for them.

A TH must establish a living donor SAC (living donor SAC) before the TH bills its first living donor transplant to Medicare. The TH develops the initial living donor SAC for each living donor organ type, by estimating the reasonable and necessary costs it expects to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period. The TH divides the estimated amount by the projected number of living donor organs to be procured by the TH, within the hospital's cost reporting period. A TH calculates its subsequent living donor SAC for each living organ type by using the transplant hospital's actual organ acquisition costs for the living donor organ type from the prior year's MCR, adjusted for any changes in the current year. The TH divides these costs by the actual number of usable living organs procured by the TH during that prior cost reporting period. Currently, when a TH/HOPO provides an organ to another transplant hospital or OPO, it must bill the receiving TH or OPO its SAC, by organ type, or the hospital's standard departmental charges that are reduced to cost. The TH/HOPO includes the actual incurred cost for organ procurement services in the organ acquisition cost center on the hospital's MCR.

Costs that may be used to develop the living donor SAC include, but are not limited to: Costs of tissue typing services, including those furnished by independent laboratories; costs of physician pre-admission transplant evaluation services; OPTN registration fees; costs for donor and recipient evaluation and workup furnished prior to admission for transplantation; other costs associated with procurement, for example, general routine and special care services related to the donor; costs of operating room and other inpatient ancillary services related to the donor; preservation and perfusion costs; and transportation costs of the excised organ. We are proposing to codify these provisions at proposed new § 413.404(b)(3)(i) in new subpart L.

(b) Cadaveric Donor Standard Acquisition Charge

In this proposed rule, we are proposing to codify Medicare's longstanding policy regarding TH/HOPO standard acquisition charges for cadaveric donors and the costs that may be included in the cadaveric donor SAC, as set forth in PRM section 3101.B, and as discussed herein, because these policies remain relevant. The cadaveric donor standard acquisition charge (cadaveric donor SAC) is an average cost that a TH/HOPO incurs to procure an organ from a cadaveric donor. The TH/HOPO calculates its initial cadaveric donor SAC for each cadaveric organ type, by estimating the reasonable and necessary costs it expects to incur in procuring cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other THs. The TH/HOPO divides this estimated amount by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the TH's cost reporting period.

The TH/HOPO calculates the subsequent cadaveric donor SAC for each cadaveric organ type, by using the transplant hospital's actual organ acquisition costs for the cadaveric donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year. The TH/HOPO divides this estimated amount by the actual number of usable cadaveric organs procured by the TH/HOPO during that prior cost reporting period.

Where the TH/HOPO provides the organ to an OPO or another TH, the TH/HOPO uses its cadaveric donor SAC to bill the OPO or the TH receiving the organ. Costs that may be used to develop the cadaveric donor SAC include, but are not be limited to: Costs of organs acquired from other THs or OPOs; costs of transportation of the excised organs; surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys); costs of tissue typing services, including those furnished by independent laboratories; preservation and perfusion costs; general routine and special care service costs; and operating room other inpatient ancillary service costs. We are proposing to codify these provisions at proposed new § 413.404(b)(3)(ii) in new subpart L.

(3) Independent OPO Standard Acquisition Charge

In this proposed rule, we are proposing to codify, at proposed new § 413.404(c) in new subpart L, Medicare's longstanding policy regarding IOPO standard acquisition charges for cadaveric donors, as set forth in PRM section 3108, and as discussed herein, because these policies remain relevant. An OPO is required under section 371(b)(1)(B) of the PHS Act (42 U.S.C. 273(b)(1)(C)) to have an agreement with the Secretary to be reimbursed under Medicare for the procurement of kidneys. The IOPO's Medicare contractor establishes the kidney SAC, which is considered an interim rate as currently specified in § 413.200(d) (proposed to be added to new subpart L as § 413.420(d)), and which consists of an estimate of the reasonable and necessary costs the IOPO expects to incur procuring cadaveric kidneys during the IOPO's cost reporting period. The contractor divides the estimated amount by the projected number of usable cadaveric kidneys procured. The IOPO's Medicare contractor may adjust the kidney SAC during the year, if necessary, for cost changes. Because the contractor must establish and may adjust, if necessary, the kidney SAC, the IOPO cannot charge or change its kidney SAC without the contractor's approval.

The Medicare contractor develops an IOPO's initial kidney SAC based on the IOPO's budget information. The kidney SAC for subsequent years is based on the IOPO's cost report, that is, costs of operating during its prior cost reporting year. These standard charges are the basis for the interim rate (that is, the kidney SAC) paid by the TH to the IOPO. When the IOPO bills the TH for its kidney acquisition services, the TH

Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.

is responsible for paying the IOPO's interim rate (that is, its kidney SAC). The IOPO's submitted cost report is used to reconcile kidney acquisition costs pursuant to § 413.200(d) (proposed to be added as § 413.420(d)).

An OPO is required under (42 U.S.C. 273(b)(1)(B)) to have accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization. As such, an IOPO establishes non-renal SACs based on its costs of procuring organs, similar to procedures set forth in section 3101, Certified Transplant Centers and Organ Acquisition Costs. An IOPO develops its SACs for each type of non-renal organs, by estimating the reasonable and necessary costs it expects to incur for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period. The IOPO divides this estimated amount by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.

When an IOPO receives an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC. The IOPO uses its own SAC and not the SAC paid to another IOPO, when billing a TH receiving the organ. For example, IOPO A has a SAC of $35,000 and IOPO B has a SAC of $50,000. IOPO A receives an organ from IOPO B and pays IOPO B their SAC of $50,000. IOPO A provides the organ to the TH and bills the TH its SAC of $35,000.

d. Accounting for Outpatient Costs and Laboratory Services

Outpatient costs including pre-transplant evaluation service costs were described for kidneys in ILs, as well as in the Medicare Claims Processing Manual and in a CMS Change Request.[1481] After non-renal organs were covered for transplantation through a CMS Ruling (for heart transplants) and through NCDs (other non-renal organs),[1482] payment policies were subsequently implemented through notice-and-comment rulemaking.[1483]

(1) Outpatient Costs

Section 3102.A. of the PRM describes how to account for certain hospital outpatient costs applicable to a potential organ transplant. The TH's organ acquisition costs include donor and recipient work-ups furnished prior to admission and costs of services rendered by interns and residents not in an approved teaching program. These costs would typically be billed to Medicare Part B. However, these costs are predominantly cadaveric donor related, incurred without an identifiable beneficiary, and are included in the TH's organ acquisition cost center.

(2) Pre-transplant Evaluation and Laboratory Services

Section 3102.C. of the PRM specifies that pre-transplant evaluation services for recipients and donors provided by the TH, including laboratory services, are paid through the organ acquisition costs of the TH. When pre-transplant laboratory tests are performed by the TH, the TH accumulates these costs in its organ acquisition cost center. The TH also includes the reasonable charges paid for physician tissue typing services provided to living donors and recipients.

(3) Histocompatibility Laboratory Services

Histocompatibility laboratories are required by the statute at section 1881(b)(2)(A) of the Act to be paid on a reasonable cost basis, in accordance with section 1861(v) of the Act. 42 CFR 413.200 sets forth the payment policy for services furnished by histocompatibility laboratories in connection with kidney acquisition and transplantation. When the laboratory services are performed by a histocompatibility laboratory, the Medicare contractor establishes interim rates which are used by the laboratory in billing a TH. The contractor disseminates information on the interim rates to all THs, OPOs, and other contractors, or posts the information on its website. The TH pays the laboratory the approved interim rate. When the laboratory bills an OPO for services, the OPO is responsible for paying the interim rate. The contractor determines the final payment to the histocompatibility laboratory for kidney-related transplant tests by reconciling interim payments and reasonable costs during final settlement of the MCR.

e. Accounting for the Cost of Services Provided to Living Kidney Donors

Section 1881(d) of the Act sets forth Medicare coverage for living kidney donors. Under section 1881(d) of the Act, any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of Medicare with respect to such donation. The Act requires that reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions), in such manner as may be prescribed by the Secretary in regulations,[1484] for all reasonable preparatory, operation, and postoperation recovery expenses associated with such donation. It further provides that payments for postoperation recovery expenses shall be limited to the actual period of recovery. Medicare's coverage is limited to those donor expenses that are incurred directly in connection with the kidney donation.

(1) Hospital Services to a Living Kidney Donor

When a living donor is admitted to a hospital (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, costs of all hospital services applicable to medical evaluation are considered kidney acquisition costs. When the living donor subsequently enters the hospital for the actual excision, the hospital costs of services rendered to the donor will continue to be treated as kidney acquisition costs under Part A.[1485]

The donor of a kidney for a Medicare transplant is covered for an unlimited number of days of inpatient care in connection with the organ removal operation. Days of inpatient hospital care used by the donor in connection with the organ removal operation are not charged against either party's utilization record.

(2) Physician Services to a Living Kidney Donor

When a living donor is admitted to a hospital (before admission for excising the donor kidney) for a medical

[1481] Part A Intermediary Letter, July 01, 1973 No. 73–25 and Part B Intermediary Letter, No. 73–22; July 1973; Medicare Claims Processing Manual (IOM 100–04, chapter 3, section 90.1.1.A. (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*); and change request 6978, available at (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2008CP.pdf*).

[1482] See CMS Ruling 87–1, April 1987; National Coverage Determinations Manual, IOM 100–03, chapter 1, Part 4, section 260 (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf*).

[1483] 52 FR 33034, September 1, 1987 (heart); 55 FR 8545, March 8, 1990 and 56 FR 15013, April 12, 1991 (liver); 60 FR 6537, February 2, 1995 (lung); 64 FR 41497, July 30, 1999 (pancreas); 66 FR 39828, August 1, 2001 (intestine, with reasonable cost coverage of acquisition costs beginning October 1, 2001).

[1484] 42 CFR 409.18, 42 CFR 409.89 (Part A); 42 CFR 410.55, 42 CFR 410.163 (Part B).

[1485] 42 CFR 409.18.

evaluation in anticipation of a kidney donation, costs of all physicians' services applicable to medical evaluation are considered kidney acquisition costs. When a living donor is admitted to a hospital for the kidney excision, physician services are no longer considered kidney acquisition costs and are not reimbursable under Part A. Under the Medicare Physician Fee Schedule, surgical excision of living donor kidneys is included in the global surgery policy, with a reasonable post-surgical follow-up defined as 90 days.[1486] This standard 90-day post-operative period includes all services by the primary surgeon during this period unless the service is for a condition or issue unrelated to the diagnosis for which the surgery is performed or is for an added course of treatment other than normal recovery from the surgery. During the donor's inpatient stay for the excision surgery and during any subsequent donor inpatient stays resulting from a direct complication of the organ donation, physician services are billed under Part B. They are billed in the normal manner but under recipient's MBI at 100 percent of the fee schedule,[1487] with no deductible or coinsurance.[1488]

(3) Living Kidney Donor Follow-Up

Costs incurred by the TH for routine kidney donor follow-up care are included in the TH's organ acquisition cost center.

For routine follow-up care, the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Beyond the reasonable and necessary 90-day global payment period, routine follow-up services are billed to Part B using the recipient's MBI. Routine follow-up services billed to Medicare by a physician other than the operating physician for up to 3 months following donation surgery must be billed using the recipient's MBI. The Medicare Administrative Contractor will review claims for services rendered more than 3 months after kidney donation surgery. Medicare may cover routine follow-up examinations up to 6 months after the kidney donation to monitor for possible complications. In all of these situations, the kidney donor is not responsible for co-insurance or deductible amounts.[1489]

The OPTN policy provides for follow-up visits, which occur at 6 months, 12 months, and 24 months post-donation. These follow-up visits are not allowable nor reportable as organ acquisition costs on the MCR and cannot be billed to Medicare. These follow-up visits are for collecting longer term data on the effects of living donation on the donor rather than for meeting medical needs of the donor.[1490]

(4) Proposals Related to Living Kidney Donor Complications

Living kidney donor complications related to the surgery to remove a kidney, which occur after the date of discharge, are not considered kidney acquisition costs. Living kidney donor complications are statutorily authorized to be paid under Part A or Part B in section 1881(d) of the Act, with no liability for deductibles or coinsurance.[1491] In accordance with IL 73–25,[1492] Medicare covers costs incurred for living kidney donor complications only if they are directly attributable to the kidney donation. Costs incurred for complications arising after the kidney donor's discharge date are billed under the Medicare transplant recipient's MBI, including facility costs and physician services. The contractor reviews costs for kidney donor complications billed under the transplant recipient's MBI. We are proposing to codify this longstanding policy by adding 42 CFR 413.402(c) to new subpart L.

f. Accounting for the Cost of Services Provided to Transplant Recipients

Certain costs related to organ transplant recipients are not organ acquisition costs, but instead are billed under Part B to the transplant recipient's MBI. These costs include standard backbench preparation services; physician services for the surgeon who performs the transplant (and sometimes performs other surgical procedures at the time of the transplant) and provides 90 days of post-operative surgical care;[1493] and/or immunosuppressant therapy management; and recipient laboratory services which occur after discharge from the hospital. See the Medicare Claims Processing Manual, IOM 100–04, chapter 12, sections 30.6.3, 40.1, and 40.4 for more details on these services.[1494]

g. Proposed Codification of Statutory Provisions Related to Pancreata Used for Pancreatic Islet Cell Transplants

Our longstanding policies related to pancreata used for pancreatic islet cell transplants are discussed in section 3110 of the PRM. Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 [1495] (MMA) requires Medicare to pay for items and services that are reasonable and necessary routine patient care costs related to acquisition and delivery of pancreatic islet cells for transplantation into Medicare beneficiaries included in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplants. The pancreata procured for islet cell transplants require the same quality and care to procure as pancreata procured for solid organ transplants. Therefore, as described in section X.B.2.a.(2) of this proposed rule, we are proposing to define for organ acquisition payment purposes, pancreata, procured for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in an National Institute of Diabetes and Digestive and Kidney Diseases clinical trial, to be an organ. Accordingly, pancreata procured for islet cell transplants are treated as solid organs for procurement purposes, and pancreata procured for covered islet cell transplants must be assigned a full standard acquisition charge. We are proposing to codify this policy by adding § 413.406 in part 413, new subpart L, in accordance with the statute. There are other clinical trials of islet cell transplants that are not funded by the National Institute of Diabetes and Digestive and Kidney Diseases, which section 733 of the MMA explicitly prohibits Medicare from covering under title XVIII of the Act.

[1486] See Addendum B in 59 FR 63515, for CPT code 50320, which is for living donor kidney excision.

[1487] 42 CFR 410.55 and 410.163.

[1488] 42 CFR 410.55 and 410.163. See also the kidney policy for living donors, which is described in the Medicare Benefit Policy Manual 100–02, chapter 11, section 140.5, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf* and billing instructions in the Medicare Claims Processing Manual 100–04, chapter 3, section 90.1.1.F. and G., available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf.*

[1489] 42 CFR 410.163.

[1490] Information from *https://optn.transplant.hrsa.gov/resources/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/,* accessed on March 16, 2021.

[1491] Section 1881(d) of the Act; 42 CFR 409.18, 409.89 for Part A costs; 42 CFR 410.55 and 410.163 for Part B costs.

[1492] Part A Intermediary Letter, July 1, 1973, No. 73–25.

[1493] See Addendum B in 59 FR 63516, for CPT codes 50360 and 50365 for kidney transplantation.

[1494] Available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.*

[1495] Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173); 42 U.S.C. 1395l.

h. Proposed Calculation of Medicare's Share of Organ Acquisition Costs, Counting of Organs

(1) General

Medicare currently calculates its share of organ acquisition costs for THs/HOPOs by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs (the numerator) to total usable organs (the denominator) reported on the Medicare hospital cost report.[1496] To ensure that a TH/HOPO's organ acquisition costs are accurately allocated to the Medicare Program, THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their MCRs.

For IOPOs, Medicare currently calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report.[1497] Similarly, IOPOs must accurately count and report on their MCRs the number of kidneys they procure and furnish to THs or other OPOs, to ensure that kidney acquisition costs are accurately allocated to the Medicare Program.

(2) Medicare Usable Organs, Total Usable Organs, Medicare Usable Kidneys, and Total Usable Kidneys

Currently, Medicare reimburses THs/HOPOs for their reasonable costs incurred to acquire ''Medicare usable organs.'' For Medicare to calculate its share of organ acquisition costs, currently the THs/HOPOs must include the following as Medicare usable organs: [1498] (1) Organs transplanted into Medicare beneficiaries; (2) organs transplanted into Medicare beneficiaries that were partially paid by a primary insurance payor in addition to Medicare; (3) organs sent to other THs or IOPOs; (4) kidneys transplanted into Medicare Advantage beneficiaries for dates of service on or after January 1, 2021; [1499] (5) kidneys sent to United States military renal transplant centers (MRTCs) with a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988, and approved by the contractor; and (6) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial pursuant to section 733 of the MMA, as discussed in section X.B.2.g of this proposed rule.[1500] (For counting purposes, the TH/HOPO does not count pancreata procured for islet cell transplant as a solid organ, but counts the number of Medicare beneficiaries who received these islet cell injections as the proxy for Medicare usable organs. For example, if a TH/HOPO procured pancreata for islet cell transplant and injected these islet cells into three Medicare beneficiaries and four non-Medicare patients during its cost reporting period, the TH/HOPO enters three in the Medicare usable organ count, and seven in the total usable organ count, on its Medicare hospital cost report.)

Medicare does not share in the cost of acquiring organs not transplanted into Medicare beneficiaries (except those organs designated for transplant but determined to be unusable). Organs not transplanted into Medicare beneficiaries must be counted as total usable organs in the denominator of the fraction of Medicare usable organs to total usable organs. THs/HOPOs must include the following as total usable organs: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other THs or OPOs; (4) organs obtained from another OPO or transplant hospital and either transplanted or furnished to other THs or OPOs; (5) organs sent to veterans' hospitals or organs sent outside the United States pursuant to 42 CFR 413.203; (6) organs transplanted into non-Medicare beneficiaries, pursuant to § 413.203; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) organs for which the transplant was covered by a Medicare Advantage plan for dates of service prior to January 1, 2021; (9) kidneys sent to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (10) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial pursuant to the MMA,[1501] as discussed in section X.B.2.g of this proposed rule.

Medicare also currently reimburses IOPOs for their reasonable costs incurred to procure ''Medicare kidneys.'' Organ acquisition costs are not paid directly by Medicare to an IOPO. The IOPO is reimbursed for its services by the TH, subject to later reconciliation by Medicare for kidneys. Medicare currently calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys (the numerator) to total usable kidneys (the denominator) reported on the Medicare IOPO cost report. For Medicare to calculate its share of Medicare kidney acquisition costs, the IOPO must include the following as Medicare kidneys: (1) Kidneys sent to THs; (2) kidneys sent to certified OPOs; and (3) kidneys sent to United States MRTCs with a reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988, and approved by the contractor. Medicare kidneys do not include kidneys sent to VA hospitals, military hospitals, or kidneys sent to foreign countries or transplanted into non-Medicare beneficiaries, pursuant to 42 CFR 413.202.

IOPOs must also count total usable kidneys in the denominator of the fraction of Medicare usable kidneys to total usable kidneys. IOPOs must include the following in total usable kidneys: (1) Medicare usable kidneys; (2) kidneys procured with the intention to be used for research; (3) kidneys procured and furnished to other THs or OPOs; (4) kidneys procured from another OPO or transplant hospital and either transplanted or furnished to other THs or OPOs; (5) kidneys sent to veterans' hospitals or organs sent outside the United States pursuant to 42 CFR 413.203; (6) kidneys for which the transplant was covered by a Medicare Advantage plan for dates of service prior to January 1, 2021; and (7) kidneys sent to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988. Currently THs/HOPOs that excise organs and send them to other THs or IOPOs, or kidneys sent to MRTCs pursuant to an approved reciprocal sharing agreement in effect prior to March 3, 1988, are presumed to be transplanted into Medicare beneficiaries, even if they are not.

[1496] CMS Pub. 15–2, chapter 40, section 4028.

[1497] CMS Pub. 15–2, chapter 33, section 3312.

[1498] Pursuant to PRM § 3115.A. and CMS Pub. 15–2, chapter 40, section 4028.3.

[1499] Section 17006 of the 21st Century Cures Act, (Pub. L. 114–255). Section 17006(c) of the Cures Act amended section 1852(a)(1)(B)(i) of the Act to exclude coverage for organ acquisitions for kidney transplants from the Medicare benefits an MA plan is required to cover for an MA enrollee, including as covered under section 1881(d) of the Act. Effective January 1, 2021, these costs will be covered under the original Medicare FFS program. The MA kidney transplants will be included in the numerator and denominator on the MCR to determine Medicare's share of kidney acquisition costs. (85 FR 33796, 33824, June 2, 2020).

[1500] Section 733 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173)); 42 U.S.C 1395l.

[1501] Id.

Similarly, some kidneys that an IOPO procures and sends to other IOPOs, THs, or MRTCs pursuant to an approved reciprocal sharing agreement in effect prior to March 3, 1988, are presumed to be transplanted into Medicare beneficiaries, even if they are not. These categories do not have a distinction to determine whether the organs are actually transplanted into Medicare beneficiaries. In this regard, Medicare organ acquisition payment policy includes the presumption that some organs are transplanted into Medicare beneficiaries, despite the category name ''Medicare usable organs'' or ''Medicare kidneys.'' As a result, through unintended consequences, Medicare currently shares in the organ acquisition costs for some organs that are not actually transplanted into Medicare beneficiaries.

When Medicare added the ESRD benefit to Medicare coverage in 1972, Medicare presumed that most kidney transplant recipients would be Medicare beneficiaries receiving the ESRD benefit, and thus Medicare would pay a larger share of kidney acquisition costs.[1502] As Medicare added benefits for transplantation of non-renal organs and included the costs to procure non-renal organs, Medicare cost reporting instructions incorporated the presumption that the ultimate transplant recipient was unknown, but likely a Medicare beneficiary. Thus, when a TH sends an organ to another TH or to an OPO, or when an OPO sends an organ to another OPO or TH, Medicare assumed that some of the unknown transplant recipients are Medicare beneficiaries, and permits those organs to be counted as Medicare usable organs in the numerator of the fraction for Medicare usable organs to total usable organs, to be assured that Medicare is paying its share of organ acquisition costs.

However, Medicare declared its intention and a methodology to calculate its share of acquisition costs, for kidneys transplanted into Medicare beneficiaries only, in a 1978 **Federal Register** final rule with comment.[1503] Specifically, for each kidney transplant performed on a Medicare beneficiary, the transplanting hospital shall receive a prescribed amount of reimbursement from Medicare for the pre-transplantation services of an OPA [organ procurement organization] or laboratory having such an agreement. The 1978 final rule set forth that an OPO's cost report must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the *total number of Medicare beneficiaries* for whom services were furnished by the agency or laboratory, and any other necessary data to enable the intermediary to determine the reasonable cost of covered services *to Medicare beneficiaries.* [Emphasis added.] Additionally, if the intermediary determines that the interim rate payments exceeded the reasonable cost of the services furnished, then the OPA or histocompatibility laboratory *must pay the excess amount per Medicare patient* to the intermediary. [Emphasis added.] These multiple declarations in the 1978 final rule establish Medicare's intention to pay for kidney acquisition costs incurred for kidneys transplanted into Medicare beneficiaries and were originally codified at 42 CFR 405.436 and later moved to 42 CFR 413.178 (currently reserved).

The longstanding policy that Medicare must only share in organ and kidney acquisition costs for Medicare beneficiaries is also set forth in 42 CFR 413.202 and 413.203. Section 413.202 requires OPOs to separate from Medicare allowable costs, acquisition costs for procuring kidneys sent to foreign transplant centers and kidneys transplanted in non-Medicare patients. Similarly, § 413.203 requires THs to separate from Medicare allowable costs, acquisition costs for procuring organs sent to foreign transplant centers and organs transplanted in non-Medicare patients. In a 1988 proposed rule, CMS expressed belief that allowing all kidneys to be counted as Medicare kidneys was not aligned with anti-cross subsidization principles set forth in section 1861(v)(1)(A) of the Act. CMS stated that the Medicare program has always paid the total costs of OPAs [OPOs] because we assumed that all kidneys procured were for Medicare beneficiaries. However, we now realize that this assumption is incorrect and that technology has allowed a significant number of kidneys to be shipped overseas. Since the Medicare program has been paying the cost of procuring kidneys shipped overseas or transplanted into non-Medicare beneficiaries, we believe that some action needs to be taken. We believe it is necessary to amend the regulations in order to effectuate the statutory principles embodied in section 1861(v)(1)(A) of the Act. Section 1861(v)(1)(A) of the Act requires that the cost of services be borne by the appropriate payor. Accordingly, the cost associated with the kidneys not used by Medicare beneficiaries must be borne by the responsible individual or third party payor. Medicare is precluded from paying any costs associated with kidneys not used by Medicare beneficiaries. 53 FR 6672 at 6673 (March 2, 1988).

Medicare's decades-old presumption that most kidney transplant recipients are Medicare beneficiaries was also applied to non-renal organs because of the lack of organ tracking capabilities over the years and has led Medicare to reimburse THs and OPOs for organ acquisition costs for organs that were not actually transplanted into Medicare beneficiaries. Similar to the beliefs expressed in the 1988 proposed rule, we believe that organ tracking capabilities allow transplant hospitals and OPOs to discern organ recipients' health insurance payor information so that organ acquisition costs can be more appropriately assigned to the Medicare program for organs transplanted into Medicare beneficiaries. The Scientific Registry of Transplant Recipients (SRTR) [1504] collects and maintains data that identifies, among other things, transplant recipients and their health insurance payors. Data obtained from SRTR show the percentage of transplants where Medicare was the recipients' payor to all transplant recipients' payors, by organ type. We compared the SRTR data for years 2017 and 2018, to the Medicare share ratio for Medicare usable organs (including kidneys) to total usable organs, for 2017 and 2018. Table X.B.-01 reflects these data. In the majority of organ types, the SRTR percentages of transplant recipients who were actual Medicare beneficiaries were lower than the Medicare share percentages for those same years. Although there is a difference in the calendar year data from SRTR and the cost reporting fiscal year data from the MCR, these data show that the majority of SRTR's percentage of Medicare transplant recipients was less than the percentages of Medicare's share compared to 2017 and 2018 submitted MCR data from the Worksheet D–4.

[1502] Intermediary Letter 73–25 (July 1973) and 54 FR 5619, February 6, 1989.

[1503] 43 FR 58370, December 14, 1978.

[1504] Section 373 of the Public Health Service (PHS) Act requires the operation of Scientific Registry of Transplant Recipients (SRTR) to support ongoing evaluation of the scientific and clinical status of solid organ transplantation. The U.S. Congress passed the National Organ Transplant Act (NOTA; Pub. L. 98–507) in 1984.

[1505] Scientific Registry of Transplant Recipients. Request for Information. Requested on 01/29/2021.

TABLE X.B.-01. OVERALL ORGAN-SPECIFIC RATIOS, MEDICARE SHARE VS. SRTR, 2017 AND 2018[1505]

Organ Type	2017 Medicare Ratio (Medicare Usable Organs/Total Usable Organs)	2017 SRTR Ratio of Actual Transplants with Medicare as Payor	2018 Medicare Ratio (Medicare Usable Organs/Total Usable Organs)	2018 SRTR Ratio of Actual Transplants with Medicare as Payor
Kidney	68.2%	58.9%	67.8%	58.6%
Heart	42.0%	31.6%	42.8%	33.0%
Liver	39.1%	28.4%	38.6%	29.2%
Lung	44.2%	43.9%	46.6%	45.7%
Pancreas	61.6%	49.1%	58.0%	45.8%
Intestine	18.1%	14.7%	14.9%	15.4%

We are aware that the capability exists to track the location and disposition of organs, from the time organs are excised from donors until they are transplanted into recipients. Organ tracking capability allows THs and OPOs the ability to know the identity of all organ transplant recipients and the donor from whom the recipient's transplanted organ was excised. Knowing the identity of all organ transplant recipients, and the donor from whom the recipient's transplanted organ was excised, allows THs and OPOs the ability to also know whether a transplant recipient is a Medicare beneficiary. OPTN policy provides that OPOs use organ tracking capability,[1506] and some THs also optionally use organ tracking capability. Per OPTN policies, THs and OPOs report information to the OPTN on the identity of transplant recipients and donors.[1507] Additionally, the OPTN data collection forms show what data elements the OPTN currently collects.[1508] The OMB form NO. 0915–0157 collects the recipient's and payor's information for the transplant. The identity of the recipient is required to be reported. THs, histocompatibility laboratories, and organ procurement organizations enter data into the OPTN database in UNet, a centralized computer network that links all 57 OPOs, 254 THs and 150 histocompatibility labs to list patients for transplant, match patients with available donor organs and submit required OPTN data.[1509] By way of knowing the identity of the recipient, the providers can further discern whether a recipient is a Medicare beneficiary. Therefore, it is possible for THs and OPOs to report, on their respective MCRs, the number of organs and kidneys transplanted into Medicare beneficiaries, eliminating the reason for Medicare organ acquisition payment policy to presume that some organs and kidneys are transplanted into Medicare beneficiaries, when they are not.

We believe it is necessary to update Medicare organ acquisition payment policy to recognize organ tracking capabilities and the ability for OPOs and THs/HOPOs to discern the identity of the recipient into whom the excised organ is transplanted, and whether that recipient is a Medicare beneficiary. Doing so will result in Medicare more accurately paying its share of organ acquisition costs. We believe it is necessary to require that OPOs and THs report on their cost reports only organs and kidneys transplanted into Medicare beneficiaries as Medicare usable organs and Medicare kidneys, respectively. Doing so would help safeguard the Medicare Trust Fund and ensure that Medicare appropriately pays only its share of organ acquisition costs, and that acquisition costs for organs not transplanted into Medicare beneficiaries are not borne by Medicare. The Medicare reasonable cost principles, upon which Medicare organ acquisition payment policy is based, and the prohibition of cross-subsidization articulated in section 1861(v) of the Act require the cost of services be borne by the appropriate payor.

While all OPOs, and some THs, use an organ tracking capability, we believe that THs that do not use an organ tracking capability can also ascertain the exact recipient, and thus recipient's payor, when an organ is excised in their hospital and sent to another TH or OPO. We understand that some THs that do not use an organ tracking capability still track organs they send to other THs or OPOs by using manual, written methodologies. In this regard, THs can determine the organ recipient from their records and by verifying the insurance payor of the recipient with the transplant recipient's hospital. Additionally, THs can contact the OPO to which they gave the organ, and because the OPTN directs OPOs to use an organ tracking system, the OPO can relay the recipient's information and recipient's payor to the TH. Likewise, Medicare contractors, who review MCRs submitted by THs and OPOs, can confirm Medicare usable organs and Medicare usable kidneys reported by THs and OPOs with supporting documentation from provider's records.

Pursuant to § 413.202, Medicare kidneys include, for cost reporting statistical purposes and counting, kidneys procured by an OPO and sent to a MRTC for transplant, pursuant to certain long-standing arrangements that existed before March 3, 1988, approved by the contractor. However, due to organ tracking capability, and to achieve equitable treatment among all OPOs (for OPOs that do not have a long standing arrangements with military THs), and to also achieve appropriate Medicare expenditures for kidney acquisition

[1506] OPTN Policy 16, *https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.*

[1507] OPTN Policy 18, *https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.*

[1508] *https://unos.org/data/data-collection/.*

[1509] *https://unos.org/technology/unet/.*

costs, we no longer believe it is appropriate to allow such kidneys to be designated as Medicare kidneys under such arrangements. Because organ tracking capability permits OPOs the ability to know a donor's transplant recipient, and thus their payor's identity, it is no longer necessary for Medicare to continue to apply its longstanding policy to deem and count all kidneys an OPO excises at, or provides to, a MRTC as Medicare kidneys for purposes of apportioning Medicare's share of the kidney acquisition costs. Thus, we are proposing to change our regulation with respect to MRTCs.

For the reasons discussed in this section, in this proposed rule we are proposing to add § 413.408(a) to new subpart L to specify that THs/HOPOs must accurately count and report Medicare usable organs and total usable organs on their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare. We are also proposing to add § 413.408(b) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, Medicare usable organs include only organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries with dates of service after January 1, 2021), organs for which Medicare has a secondary payer liability [1510] for the organ transplant, and pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation for Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

We are also proposing to add § 413.408(c) to new Subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, total usable organs include: (1) Medicare usable organs; (2) organs excised with the intention to be used for research; (3) organs excised and either transplanted or furnished to other transplant hospitals or OPOs; (4) organs obtained from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs; (5) organs sent to veterans' hospitals or organs sent outside the United States; (6) organs transplanted into non-Medicare beneficiaries; (7) organs for which the transplant was totally or partially paid by primary insurance other than Medicare; (8) organs for which the transplant was covered by a Medicare Advantage plan for dates of service prior to January 1, 2021; (9) kidneys sent to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988; and (10) pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

We are also proposing to remove § 413.203, and add § 413.408(d) to new subpart L, so that all organ acquisition policies are housed together, to specify that a TH's total costs for all organs are reduced by the costs associated with procuring organs that are sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries; and to specify that THs must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in proposed § 413.408(e).

We are also proposing to add § 413.408(e) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, Medicare's share of organ acquisition costs for a TH/HOPO is calculated by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs transplanted into Medicare beneficiaries, as specified in proposed § 413.408(b), to total usable organs, as specified in proposed § 413.408(c).

For rules pertaining to counting kidneys and calculating Medicare's share of kidney acquisition costs for IOPOs, in this proposed rule, we are proposing to add § 413.410(a) to new subpart L to specify that IOPOs must accurately count and report Medicare usable kidneys and total usable kidneys on their Medicare IOPO cost reports to ensure that costs to acquire Medicare usable kidneys are accurately allocated to Medicare. We are also proposing to add § 413.410(b) to new subpart L to specify that, for cost reporting periods beginning on or after October 1, 2021, for IOPOs, Medicare kidneys include only kidneys transplanted into Medicare beneficiaries.

We are also proposing to add § 413.410(c) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, for IOPOs, total usable kidneys include: (1) Medicare usable kidneys; (2) kidneys procured with the intention to be used for research; (3) kidneys procured and furnished to other transplant hospitals or OPOs; (4) kidneys procured from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs; (5) kidneys sent to veterans' hospitals or organs sent outside the United States; (6) kidneys for which the transplant was covered by a Medicare Advantage plan for dates of service prior to January 1, 2021; and (7) kidneys sent to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988.

We are proposing to remove § 413.202 and add § 413.410(d) to new subpart L, to specify that an IOPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries; and to specify that IOPOs must separate costs for procuring kidneys sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in proposed § 413.410(e).

We are also proposing to add § 413.410(e) to new subpart L to specify that for cost reporting periods beginning on or after October 1, 2021, Medicare's share of kidney acquisition costs is calculated by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys, as specified in proposed § 413.410(b), to total kidneys, as specified in proposed § 413.410(c).

i. Proposals Related to Intent To Transplant, and Counting En Bloc, Research, and Discarded Organs

In this section, we are proposing to add § 413.412, to new subpart L, to specify our longstanding policies set forth in CMS Ruling 1543–R, issued December 21, 2006, and PRM–1, sections 3111 and 3115, pertaining to intent to transplant, counting en bloc organs, research organs, and discarded organs for THs and OPOs. These policies provide for the proper calculation of Medicare's share of organ acquisition costs that are used for the appropriate allocation of organ acquisition costs on the MCR. The calculation of Medicare's share of organ acquisition costs is discussed in section X.B.2.h.(1). of this proposed rule. The methodology of counting organs to calculate Medicare's share of organ acquisition costs is used for the

[1510] Medicare secondary payer is governed by section 1862(b)(2) of the Act and 42 CFR 411.20 through 411.39.

allocation of organ acquisition costs on the MCR and differs from Medicare's organ counting policy to assess OPOs' performance, which is set forth under the OPO CfCs, 42 CFR part 486, subpart G. To calculate Medicare's share of organ acquisition costs, when organ procurement is attempted, but no organ is actually retrieved (or the organ is instead discarded or donated for research), proper counting of the organ must occur to ensure that overhead costs are appropriately allocated to Medicare and non-Medicare payors. However, cost allocation is not a factor when counting organs for evaluating an OPO's performance under Medicare's CfC.

(1) Principle of Intent To Transplant

Medicare presumes that THs and OPOs intend to procure all donor organs that are medically suitable for transplant.[1511] We are proposing to add § 413.412(a)(1) to new subpart L, to specify, for organ acquisition payment purposes, an organ is intended for transplant when the OPO or TH designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s). Regardless of whether the OPO or TH procures organs for transplant, it incurred cost in attempting to procure organs.[1512] We are proposing to add § 413.412(a)(2) to new subpart L, to specify, OPOs and THs must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

(2) Counting and Cost Allocation of En Bloc Organs

Our policy for counting en bloc organs for cost allocation purposes is set forth in PRM–1 section 3115. We are proposing to add § 413.412(b) to new subpart L, to specify our policy for counting en bloc organs for Medicare cost allocation purposes and to specify that en bloc organs can be en bloc lungs or en bloc kidneys.

We are proposing to add § 413.412(b)(1) to new subpart L to specify that OPOs and THs count en bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ or one Medicare usable kidney, in accordance with the proposed Medicare organ counting policy in section X.B.2.h.(2). of this proposed rule.

We are also proposing to add § 413.412(b)(2) to new subpart L to specify that OPOs and THs count en bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ or one Medicare usable kidney, in accordance with the proposed Medicare organ counting policy in section X.B.2.h.(2). of this proposed rule.

(3) Counting and Cost Allocation of Research Organs

Our longstanding policy regarding counting of organs excised and used for research for Medicare cost allocation purposes is set forth in PRM–1 sections 3111 and 3115. We are clarifying that for organ acquisition cost allocation purposes, a ''research organ'' is an organ procured and used for research regardless of whether it is transplanted as part of clinical care (with the exception of pancreata previously discussed in section X.B.2.h.(2)) of the preamble of this proposed rule. We are proposing to add § 413.412(c) to new subpart L to specify that organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata previously discussed in section X.B.2.h.(2)). of the preamble of this proposed rule. However, we are also clarifying that Medicare shares in the costs of organs that are designated for transplant prior to the time the donor entered the hospital's operating room, but determined to be unusable and donated to research. The costs incurred are allocated amongst all remaining usable organs.

We are proposing to add § 413.412(c)(1)(i) to new subpart L to specify that OPOs and THs do not count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs. We are also proposing to add § 413.412(c)(1)(ii) to specify that OPOs and THs count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs, as total usable organs.

We are proposing to add § 413.412(c)(2) to new subpart L to specify that OPOs and THs do not count organs designated for transplant prior to the time the donor entered the hospital's operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

(4) Counting and Cost Allocation of Discarded/Unusable Organs

Our longstanding policy regarding counting of discarded/unusable organs for cost allocation purposes is set forth in CMS Ruling 1543–R issued December 21, 2006 and PRM–1 sections 3111 and 3116. We are proposing to add § 413.412(d) to new subpart L, to specify that an organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded. This includes organs that are determined to be unusable and subsequently donated to research as previously described in section X.B.2.i.(3). of this proposed rule.

j. Proposals Related to Medicare as Secondary Payer—Organ Acquisition Costs and Medicare Organ Count

If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. Medicare prohibits secondary payment if the provider is either obligated to accept, or voluntarily accepts, as payment in full, a primary payment that is less than its charges. See 42 CFR 411.32(b). When a provider or supplier is obligated to accept as full payment an amount less than its charges, Medicare considers that lower amount to be the provider's charges. (For more information see the October 11, 1989 final rule (54 FR 41728)). Medicare organ acquisition cost reimbursement policy when beneficiaries have a primary insurer other than Medicare, is set forth in PRM–1 section 3104, Accounting for the Cost of Medicare Secondary Payer. In this proposed rule, we are proposing to codify into the regulations the organ acquisition cost reimbursement policy with regard to Medicare secondary payer policy, as set forth in PRM–1 section 3104.

To determine whether the provider is contractually obligated to accept the primary insurer's payment as payment in full, and thus whether Medicare has zero liability as a secondary payer, it is necessary to review the provider or

[1511] CMS Ruling 1543–R (December 2006), and the PRM 15–1, chapter 31, sections 3111 & 3115.

[1512] The PRM 15–1, chapter 31, and PRM 15–2, chapter 33, section 3306 and chapter 40, section 4028 set forth our current, longstanding policies regarding the counting of organs for Medicare organ acquisition payment purposes.

supplier's agreement with the primary insurer. If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not counted as a Medicare usable organ.

When the primary insurer's agreement does not require the provider to accept the payment from the primary insurer as payment in full and the payment the provider receives from the primary insurer for the transplant and the organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs. To determine whether Medicare has a secondary payer liability, it is necessary for the provider to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer. The provider's Medicare remittance advice may or may not show that Medicare has a liability because the remittance advice only reflects the transplant portion of the payment. Thus, the provider will need to compare the total Medicare cost (the transplant DRG and the organ acquisition costs) to the payment from the primary payer to determine whether Medicare has a liability for the organ acquisition costs. If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the organ must not be counted as a Medicare usable organ. If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and the organ is counted as a Medicare usable organ. In this circumstance, the payment from the primary payer is pro-rated between the transplant DRG payment and the organ acquisition payment. If the organ is counted as Medicare usable, the organ acquisition portion of the primary payment must be included on the appropriate line as a revenue offset on the TH's MCR (currently Form CMS–2552). This is consistent with the cost reporting instructions in CMS Pub. 15–2, (PRM–2) chapter 40, section 4028.

Consider the following example as an illustration of Medicare's payment of organ acquisition costs as a secondary payer. A TH transplants a patient that has private health insurance and Medicare. The private health insurance is primary and Medicare is secondary. The private health insurance pays the TH $70,000 for the transplant and the organ acquisition costs; there is no requirement in the primary insurer's agreement with the provider for the TH to accept this payment as payment in full. If Medicare was the primary payer, the combined payment to the TH would have been $100,000 ($60,000 for the transplant and $40,000 for the organ acquisition costs). The TH compares the primary payer payment to the total amount Medicare would have paid if it had been primary (the transplant DRG and organ acquisition costs). The TH prorates the primary payer's payment of $70,000 between a portion of the transplant DRG and a portion of the organ acquisition costs. The TH determines the primary payer amount for the transplant DRG payment is $42,000 ($70,000 payment from the primary payer × [$60,000 for the transplant portion from Medicare/$100,000 combined Medicare payment]) and for organ acquisition costs is $28,000 ($70,000 payment from the primary payer × [$40,000 for the organ acquisition portion from Medicare/$100,000 combined Medicare payment]). The TH counts the organ as a Medicare usable organ on its MCR and offsets the primary payment amount ($28,000) as revenue received, thereby reducing Medicare's liability. In this proposed rule, we are proposing to add § 413.414(a) to new subpart L to set forth the general principle that if a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. To determine whether Medicare has liability as a secondary payer for organ acquisition costs, it is necessary to review the TH's agreement with the primary insurer.

We are also proposing to add § 413.414(b) to new subpart L to set forth the circumstances when Medicare has no secondary payer liability for organ acquisition costs. If the primary insurer's agreement requires the TH to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ. We are also proposing to add § 413.414(c) to new subpart L to set forth the policy for when Medicare may have a secondary payer liability for organ acquisition costs, which is based upon the provider's agreement with the primary insurer that does not require the provider to accept the payment from the primary insurer as payment in full, and the payment from the primary payer for the transplant and the organ acquisition costs is less than the provider's costs for the transplant and the organ acquisition costs. When the primary insurer's agreement does not require the TH to accept the payment from the primary insurer as payment in full and the payment the TH receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs. To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the TH to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer. If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the organ cannot be counted as a Medicare usable organ. If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and the organ is counted as a Medicare usable organ. In this circumstance, the payment from the primary payer is pro-rated between the transplant DRG payment and the organ acquisition payment and the portion of the payment applicable to organ acquisition will be used on the cost report to reduce the Medicare organ acquisition costs.

k. Proposed Organ Acquisition Charges for Kidney Paired Exchanges

In a directed living kidney donation, the donor names a specific recipient who will receive the donor's kidney.[1513] Because the donor and recipient are known prior to the organ excision and transplantation, the organ acquisition costs can be appropriately and accurately matched to the recipient's account. In a non-directed donation, the donor does not name a specific recipient for the kidney and instead, the donor is matched with a recipient in need.[1514]

[1513] *https://www.kidney.org/transplantation/livingdonors/general-information-living-donation.*

[1514] Id.

Kidney paired exchanges are similar to directed living donations; however when the living donor and recipient do not match, they can consent to participate in a kidney paired exchange program. Kidney paired exchanges can occur when two or more living donor/recipient pairs match each other and the donated kidneys from two or more donors are exchanged so each recipient receives a compatible kidney for transplantation.

In a kidney paired exchange, the living donor and matched recipient may have their procedures performed at different THs. When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all. The Medicare organ acquisition payment policy for kidney paired donations is currently set forth at PRM section 3106. In this proposed rule, we are proposing to codify Medicare's organ acquisition payment policy with respect to KPD transactions to ensure that the kidney acquisition costs in a kidney paired exchange are documented so that the kidney acquisition costs are appropriately and accurately assigned to the transplant recipient's account, and appropriate organ acquisition payment outcomes are achieved, consistent with a directed donation.

The costs of all hospital and physician services for pre-transplant living donor and recipient evaluations become acquisition costs and are included in the MCR of the recipient's TH, regardless of whether the recipient is a Medicare beneficiary. Additionally, all total usable kidneys and all Medicare usable kidneys are recorded by the transplant hospital on its MCR so that Medicare's share of kidney acquisition costs can be computed; this is true regardless of whether the transplant results from a KPD or from a directed donation. In a kidney paired exchange, once the donor and recipient are matched, any additional tests requested by the recipient's TH, and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's MCR, regardless of whether an actual donation occurs, and regardless of whether the recipient is a Medicare beneficiary. When a donor's TH procures and sends a kidney to a recipient's TH, the donor's TH bills the recipient's TH the donor TH's kidney SAC, or alternatively, its standard departmental charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney. The donor's TH records these costs on its MCR as kidney acquisition costs and offsets any payments received from the recipient's TH against its kidney acquisition costs. The recipient's TH records as part of its kidney acquisition costs, the amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ, as well as any additional testing performed and billed by the donor's TH.

In the scenario where a donor's TH does not procure a kidney, and instead the donor travels to the recipient's TH and the recipient's TH procures the organ from the donor, the reasonable costs associated with the organ procurement are included on the MCR of the recipient's TH. As discussed in section X.B.2.b.(3). of this proposed rule, transportation and travel expenses of the living donor are not allowable Medicare costs. Under 42 U.S.C. 273(b)(3), the cost of transportation of donated organs to the TH are organ acquisition costs. Programs outside of Medicare, such as that of the National Living Donor Assistance Center, may pay for transportation costs for living donors.

Example. The following is an example of the accounting of organ acquisition costs in a kidney paired exchange for Medicare cost reporting purposes.

(Step 1), the Participants. There are 4 THs: TH A, TH B, TH C, and TH D. Each TH has a potential transplant recipient in need of a kidney and each recipient has a willing, but poorly matched, donor; thus, all donors and recipients enter into a kidney paired exchange. Each recipient and donor pair has been evaluated at their respective TH.

- *TH A.* Recipient A is a patient of TH A. TH A evaluates three potential living donors for Recipient A before a donor, Donor A, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH A's cost report. Recipient A and Donor A do not match each other but both agree to participate in a KPD exchange.
- *TH B. Recipient B is a patient of TH B.* TH B evaluates two potential living donors for Recipient B before a donor, Donor B, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH B's cost report. Recipient B and Donor B do not match each other but both agree to participate in a KPD exchange.
- *TH C.* Recipient C is a patient of TH C. TH C evaluates three potential living donors for Recipient C before a donor, Donor C, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH C's cost report. Recipient C and Donor C do not match each other but both agree to participate in a KPD exchange.
- *TH D.* Recipient D is a patient of TH D. TH D evaluates three potential living donors for Recipient D before a donor, Donor D, is identified. The costs of these evaluations are reported as kidney acquisition costs on TH D's cost report. Recipient D and Donor D do not match each other but both agree to participate in a KPD exchange.

(Step 2), the KPD Match. Through the KPD exchange it is determined that Recipient A matches Donor C; Recipient B matches Donor D; Recipient C matches Donor A; and Recipient D matches Donor B.

(Step 3), After the KPD Match.

- Recipient C's TH requests Donor A's TH perform an additional test that was not included in Donor A's initial evaluation. Donor A's TH performs the additional test and bills Recipient's C's TH, charges reduced to cost, for the additional tests of Donor A. The amounts billed by TH A to TH C are included in TH C's MCR as organ acquisition costs for Recipient C.
- Donor B elects to travel to TH D for the procurement and any additional testing. (Note: The cost of travel for a living donor is not an allowable organ acquisition cost.)
- Donor A, Donor C, and Donor D remain at their original intended recipients' THs (TH A, TH C and TH D, respectively) where they were evaluated and where their organ procurement will occur.

(Step 4), Procuring, Packaging and Transporting the Kidneys.

- TH A procures Donor A's kidney and packages and transports it to TH C for Recipient C. TH A bills TH C, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by TH C that was not included in the initial evaluation of Donor A. Donor A's TH records these costs on its MCR as kidney acquisition costs and offsets any payments received from TH C against its kidney acquisitions costs.
- TH B does not procure a kidney. Donor B elects to travel to TH D for the procurement. TH D procures Donor B's kidney and records these costs on its cost report as kidney acquisition costs. TH B receives a kidney from TH D for transplant into recipient B. TH B records the amounts it pays to TH D on TH B's MCR as kidney acquisition costs.

• TH C procures Donor C's kidney and packages and transports it to TH A for Recipient A. TH C bills TH A, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney as well as any additional testing requested by TH A that was not included in the initial evaluation of Donor C. Donor C's TH records these costs on its MCR as kidney acquisition costs and records any payments received from TH A on TH C's MCR to offset its kidney acquisitions costs.

• TH D procures Donor D's kidney and packages and transports it to TH B for recipient B. TH D bills TH B, charges reduced to cost, for the reasonable costs associated with procuring, packaging and transporting the kidney, as well as any additional testing requested by TH B that was not included in the initial evaluation of Donor D. Donor D's TH records these costs on its MCR as kidney acquisition costs and records any payments received from TH B on TH D's MCR to offset its kidney acquisitions costs. TH B records the amounts it pays to TH D for Donor D's kidney on TH B's MCR as kidney acquisition costs.

(Step 5), Counting Medicare Usable Organs. Because of the proposed policy in section X.B.2.h. of the preamble of this proposed rule and proposed new § 413.408 for Medicare usable organ counting, all organs that are transplanted into Medicare beneficiaries are counted as Medicare usable kidneys.

The following tables summarize the KPD exchange described previously.

TABLE X.B.-02. SUMMARY OF KIDNEY PAIRED DONATION EXCHANGE EXAMPLE

	TH A	TH B	TH C	TH D
Recipient	Recipient A	Recipient B	Recipient C	Recipient D
Number of evaluations	Evaluates 3 potential donors before Donor A is identified.	Evaluates 2 potential donors before Donor B is identified.	Evaluates 3 potential donors before Donor C is identified.	Evaluates 3 potential donors before Donor D is identified.
Donor	Donor A	Donor B	Donor C	Donor D
	Recipient A and Donor A do not match each other but agree to a KPD exchange.	Recipient B and Donor B do not match each other but agree to a KPD exchange.	Recipient C and Donor C do not match each other but agree to a KPD exchange.	Recipient D and Donor D do not match each other but agree to a KPD exchange.
KPD match	Recipient A matches with Donor C.	Recipient B matches with Donor D.	Recipient C matches with Donor A.	Recipient D matches with Donor B.
After the match	TH A performs additional tests and procures kidney from Donor A for TH C.	TH B does not procure kidney from Donor B for TH D. Donor B travels to TH D.	TH C procures kidney from Donor C for TH A.	TH D procures kidney from Donor D for TH B. Donor B travels to TH D for the kidney procurement.

TABLE X.B.-03. SUMMARY OF ACCOUNTING FOR KIDNEY PAIR DONATION EXAMPLE

Accounting				
Cost of evaluations	$12,000 incurred by TH A	$9,000 incurred by TH B	$15,000 incurred by TH C	$20,000 incurred by TH D
Counting Medicare usable kidneys	2 Medicare usable kidneys: 1 kidney procured/ sent and 1 kidney received/ transplanted.	1 Medicare usable kidney: 1 kidney received/transplanted.	2 Medicare usable kidneys: 1 organ procured/sent and 1 kidney received/transplanted.	2 Medicare usable kidneys: 1 kidney procured/sent and 1 kidney procured/transplanted.
Donor costs associated with procuring, packaging and transporting the kidney to the recipient TH s	TH A bills TH C $18,000 for costs incurred to procure Donor A's kidney.	No bills sent to TH D.	TH C bills TH A $10,000 for costs incurred to procure Donor C's kidney.	TH D bills TH B $14,000 for costs incurred to procure Donor D's kidney.
Recipient costs associated with procuring, packaging and transporting the kidney bill by Donor THs	TH A receives a bill from TH C for $10,000 for costs incurred to procure Donor C's kidney.	TH B receives a bill from TH D for $14,000 for costs incurred to procure Donor D's kidney.	TH C receives a bill from TH A for $18,000 for costs incurred to procure Donor A's kidney.	No bills received from TH B. TH D claims all costs after initial evaluation for Donor B.
Kidney acquisition costs recorded on MCR Subtotal	$12,000 evaluation costs of TH A $18,000 for costs billed to TH C $10,000 billed from TH C $40,000	$9,000 evaluation costs of TH B $14,000 billed from TH D $23,000	$15,000 evaluation costs of TH C $10,000 for costs billed to TH A $18,000 billed from TH A $43,000	$20,000 evaluation costs of TH D $14,000 for costs billed to TH B $8,000 for costs incurred to procure Donor B's kidney at TH D. $42,000
Offset on MCR amounts received from recipient TH. Amounts in ( ) denote a negative number.	($18,000) received from TH C	No payment received from TH D	($10,000) received from TH A	($14,000) received from TH B
Net cost recorded on MCR	**$22,000**	**$23,000**	**$33,000**	**$28,000**

In this proposed rule, we are proposing to codify into the regulations the Medicare organ acquisition payment policy for kidney paired exchanges, as set forth in PRM section 3106. Consistent with this proposal, we are proposing to add § 413.416(a) to new subpart L to specify that when a recipient and donor elect to participate

in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's TH, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all. We are also proposing to add § 413.416(b) to new subpart L to specify that in a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's TH and performed by the donor's TH, are billed to the recipient's TH as charges reduced to cost (using the donor's TH's cost to charge ratio) and included as acquisition costs on the recipient TH's MCR. We are also proposing to add § 413.416(c) to new subpart L to specify that in a kidney paired exchange, when a donor's TH procures and sends a kidney to a recipient's TH, all costs must be reasonable and necessary and (1) the donor's TH bills the recipient's TH the donor TH's charges reduced to cost or the TH's applicable SAC for the reasonable costs associated with procuring, packaging and transporting the kidney; (2) the donor's TH records these costs associated with procuring, packaging and transporting the kidney on its MCR as kidney acquisition costs and offsets any payments received from the recipient's TH against these kidney acquisition costs; and (3) the recipient's TH records as part of its kidney acquisition costs, the amounts billed by the donor's TH for the reasonable costs associated with procuring, packaging, and transporting the organ as well as any additional testing performed and billed by the donor's TH. We are also proposing to add § 413.416(d) to new subpart L to specify that, in a kidney paired exchange (1) when a donor's TH does not procure a kidney, but the donor travels to the recipient's TH for the organ procurement, the reasonable costs associated with the organ procurement are included on the MCR of the recipient's TH, and (2) travel expenses of the living donor are not allowable Medicare costs. In section X.B.2.c.(2). of this proposed rule, we are proposing to add § 413.404(b)(2) to specify that when a transplant hospital/HOPO provides an organ to another transplant hospital or OPO, it must bill the receiving transplant hospital or OPO its SAC or the hospital's standard departmental charges that are reduced to cost.

l. Proposals Requiring Donor Community Hospitals To Charge OPOs Reasonable Costs, Charges Reduced to Cost

Medicare-certified hospitals that are not THs but collaborate with OPOs to procure organs from cadaveric donors for transplantation are hereinafter referred to as ''donor community hospitals''. To participate in the Medicare Program, donor community hospitals and THs have organ procurement responsibilities and must have an agreement with a designated OPO to timely notify the OPO of individuals whose death is imminent or who have died in the hospital (42 CFR 482.45(a)(1)). The OPO then implements its donation protocol and, when appropriate (after declaration of death and consent to donate), will arrange for the procurement of all medically suitable cadaveric donor organs for transplant, at the donor community hospital or TH. In this regard, donor community hospitals and THs may incur costs for services provided to cadaveric organ donors following the consent to donate through the procurement of the organs (for example, use of the hospitals operating room, staff, and ventilators to maintain the viability of the cadaveric donor organs).

Currently, when a donor community hospital incurs costs for services provided to the cadaveric donor, as authorized by the OPO following the declaration of death and consent to donate, it bills the OPO its customary charges (not reduced to cost) or a negotiated rate. (PRM–1 section 3107). Donor community hospital billing procedures are described in IL 74–23, published July 1, 1974, which provides, ''where the excising hospital is not a TH, it will bill its customary charges for those services used in excising the cadaver kidney.'' Thereafter, the OPO includes the charges from the donor community hospital on its cost report as part of the OPO's organ acquisition costs. At the end of its accounting period, the TH/HOPO uses these amounts to calculate its renal and non-renal SAC amounts for the following year, and the IOPO uses these amounts to calculate its non-renal SAC amounts for the following year. Medicare contractor's also use these amounts to calculate the IOPO's kidney SAC for the following year.

When the IOPO furnishes an organ to a TH (or other OPO), the IOPO bills the TH (or other OPO) the IOPO's SAC for the specific organ type. Currently, when a TH/HOPO provides an organ to another TH or OPO, it must bill its SAC or its standard departmental charges reduced to cost. The OPO's SAC is a charge which reflects an average of the total actual costs the OPO incurs to furnish an organ and reflects amounts the OPO is charged by the donor community hospital for services the donor community hospital provides to cadaveric donors. THs then include these SACs they have paid to OPOs to procure organs as allowable acquisition costs in their bills to Medicare, which Medicare pays. Therefore, because the OPO's incurred costs are passed on to and paid by the TH, and because the TH then includes these amounts as organ acquisition costs on its cost report, this chain of incurred costs results in Medicare paying these donor hospital charges (that are not reduced to cost) when it reconciles the organ acquisition costs on the TH cost report.

Stakeholders have made CMS aware that some donor community hospitals are charging OPOs amounts that are in excess of reasonable costs for services provided to cadaveric organ donors, resulting in Medicare paying more than reasonable costs for the acquisition of cadaveric donor organs for transplant. In one instance, an OPO identified a donor community hospital in its designated service area that billed amounts in excess of reasonable costs. CMS reviewed the donor community hospital's bills to the OPO and the donor community hospital's MCR information to evaluate the costs associated with those charges. CMS computed, using the hospitals cost-to-charge ratios, that the charges billed by the donor community hospital in the amount of $194,000, equated to a cost of $11,000. Thus, the donor community hospital's actual costs were approximately 6 percent of their billed charges.

Organ acquisition costs are reimbursed under Medicare's principles of reasonable cost established under section 1861(v) of the Act. Donor community hospitals (and THs) are Medicare-certified hospitals and must follow Medicare's reasonable cost principles under section 1861(v) of the Act. Because the services donor community hospitals provide to cadaveric donors, and thus charge to OPOs, are included as organ acquisition costs on OPOs' cost reports, these charges should also be subject to Medicare's principles of reasonable cost established under section 1861(v) of the Act, and 42 CFR 413.5 and 413.9.

In a 1978 final rule with comment, CMS similarly noted that THs have no basis for determining the reasonableness

of the charges made by the OPO.[1515] CMS observed that services furnished by OPOs, if they are not part of the transplant hospital, are billed to transplant hospitals, which pay the charges shown on the bill. The charges then become allowable costs of the hospitals.[1516] When donor community hospitals charge OPOs amounts not reduced to costs, and the OPOs pay the charges shown on the bill, those charges become incorporated as organ acquisition costs to the TH and are subsequently shared by Medicare; thus, Medicare's reasonable cost principles applicable to organ acquisition costs are not observed. We note that organs recovered from donor community hospitals comprised 62 percent of all transplanted organs in 2017 and 2018.[1517] We recognize that because THs bill the OPOs' charges to Medicare, Medicare is paying more than reasonable costs for these services that become organ acquisition costs.

Because these charges become allowable organ acquisition costs of the TH, we believe that donor community hospitals should be required to reduce their charges to cost for services provided to cadaveric donors and billed to OPOs, in accordance with reasonable cost principles given in section 1861(v) of the Act and in our regulations at 42 CFR 413.5 and 413.9. Doing so will result in conformance to Medicare reasonable cost principles, and result in reduced costs to the OPOs, subsequently reducing cadaveric donor SACs billed to THs or OPOs, which may benefit other payors, as well as Medicare. Donor community hospitals are reimbursed either a DRG payment by Medicare (if the patient is a Medicare beneficiary), or a payment from other payers, for services provided to a potential organ donor prior to declaration of death and consent to donate. For services provided after declaration of death and consent to donate payment, if our proposal is implemented, donor hospitals would be reimbursed by OPOs for their reasonable costs in accordance with Medicare's principles of reimbursement. Therefore, a donor community hospital would see a reduction in reimbursement from OPOs, because the donor hospital was previously permitted to bill the OPO its customary charges or negotiated rates. However, donor community hospitals would still have their reasonable costs reimbursed.

We believe that an equitable and accurate methodology to reduce a donor community hospital's charges to cost would be to use the most recently available hospital specific CCR. Using the hospital's specific CCR would be unique to each donor community hospital and would more accurately compensate them for services provided to cadaveric organ donors, as opposed to using an alternative like the statewide CCR. Because contractors recalculate each hospital's specific CCR on an ongoing basis, whenever more recent cost report data is available, the hospital's specific CCR is arguably more accurate and more closely aligned with creating a uniform charge to cost structure.

One methodology we considered to reduce a donor community hospital's charges to cost was to require them to use their statewide average operating CCR and apply this statewide average CCR to its charges. The statewide average operating CCR is updated annually in the FY IPPS/LTCH rule and is a transparent source of data. We note that the statewide average operating CCR published in the FY 2021 IPPS/LTCH final rule was 0.272 for urban hospitals and 0.336 for rural hospitals. Using a statewide average CCR would even out any instances in which a hospital's operating costs fall above or below established parameters. However, because it is an average, it would not accurately represent the variability in actual hospital specific CCRs. Therefore, using a statewide CCR may not adequately serve the purpose of reducing charges to cost.

Stakeholders have suggested that some donor community hospitals are improperly billing OPOs for services provided to cadaveric donors *prior* to the declaration of death and consent to donate. This would be inappropriate because hospital services provided prior to declaration of death and consent to donate are billable to the donor's insurance in the same manner hospital services are billable to an individual receiving services, regardless of whether the payor is Medicare. We reiterate that when a donor community hospital or TH incurs costs for providing services to a cadaveric donor, as authorized by the OPO, only those costs incurred after the declaration of the donor's death and consent to donate are permitted to be billed to the OPO. The OPO must accept bills from donor community hospitals and THs for costs only incurred after the declaration of death and consent to donate. Contractors will review OPO cost reports to ensure that donor community hospitals and THs charge OPOs for cadaveric donor costs incurred after declaration of death and consent to donate.

In this proposed rule we are proposing to add § 413.418(a) in new subpart L, to specify that a donor community hospital (a Medicare-certified non-transplant hospital) incurs organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate.

We are proposing to add § 413.418(b) in new subpart L, to specify that for cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered.

m. Proposed Revisions, Technical Corrections, and Conforming Changes to 42 CFR Part 412, Subparts A, E, G, and H and to Part 413, Subparts A, C, and H

(1) Conforming Changes to Terminology in 42 CFR Parts 412 and 413

In section X.B.2.a.(1). of the preamble of this proposed rule, we noted terminology differences in the use of ''transplantation center'', where the regulations in 42 CFR part 412, subparts A, E, G, and H and in Part 413, subparts A, C, and H use the term to mean an organ-specific transplantation program that is within a TH. We are proposing to conform the language in the regulation text to the terminology used in the CoPs at § 482.70 by replacing the term ''transplantation center'' and its various permutations with the term ''transplant program'' and its various permutations. We are proposing to make this conforming change in the text of the following regulations: §§ 412.1(a)(1)(ii), 412.2(e)(4), 412.71(b)(3), 412.90(d), 412.100 (in the title and in the text at §§ 412.100(a)(1)), 412.113(d), 412.116(c), and 413.40(a)(3). We are also proposing to update the terminology to replace ''organ procurement agency'' and its various permutations with ''organ procurement organization'' and its various permutations. Further, we are proposing to replace the acronym ''OPAs'' with ''OPOs''. We are proposing to make these terminology changes to the regulation text at §§ 412.100(b) and 413.1(a)(2)(v) to conform to the terminology used in the CoPs found in 42 CFR part 482. Finally, we are proposing to change ''renal'' to ''kidney'' in §§ 412.71(b)(3), 412.90(d), in the title and paragraph (a) of § 412.100, and in § 412.116(c), to

[1515] 43 FR 58370 (December 14, 1978).

[1516] Id.

[1517] Scientific Registry of Transplant Recipients. Request for Information. Requested on 02/08/2021.

conform to the terminology used in the CoPs at § 482.104.

(2) Revisions, Technical Corrections, and Conforming Changes to § 412.100

We are proposing to revise the text currently found in § 412.100(a) and (b) to change ''expenses'' to ''costs'' and to remove the word ''estimated'' from § 412.100(a)(1). We are also proposing to make a technical correction to remove from § 412.100(a)(1) cross-references to CoPs which no longer exist, and replace them with § 482.104 and are proposing to add language to clarify that CMS adjusts inpatient prospective payment system (IPPS) rates for inpatient operating costs. We are proposing to revise § 412.100(a)(1) to read CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104) to remove the net costs associated with kidney acquisition.

Additionally, we are proposing to revise § 412.100(a)(2) to clarify the language, and to specify that Medicare payment for kidney acquisition costs includes only those costs for kidneys transplanted into Medicare beneficiaries. We are proposing to revise § 412.100(a)(2) to specify the following:

- Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.
- IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

In section X.B.2.b.(1). of the preamble of this proposed rule, we are proposing to revise § 412.100(b) by revising and relocating the list of organ acquisition costs given in that paragraph and adding the list as paragraph (b) in proposed § 413.402 of new subpart L. Further, we are proposing to revise § 412.100(b) to make it clearer that kidney acquisition costs must be incurred. Finally, we are proposing to revise § 412.100(b) to add language that the items and services covered as kidney acquisition costs are specified in § 413.402(b).

(3) Proposed Revisions and Conforming Changes to 42 CFR 412.113(d)

In addition to the conforming change discussed in section X.B.2.m.(1). of the preamble of this proposed rule, we are proposing to revise the regulation text at § 412.113(d) to reference the organ acquisition policies given in new subpart L of part 413, rather than to maintain the existing cross-reference to the definition of organ given in § 486.302.

(4) Technical Corrections and Conforming Changes to § 413.1

In addition to the conforming change discussed in section X.B.2.m.(1). of the preamble of this proposed rule, we are proposing to revise the text in § 413.1(d)(2)(i) to put it into list form. We are also proposing to revise the text related to kidney acquisition costs to read organ acquisition costs as specified in part 413 subpart L.

(5) Proposed Revision to 42 CFR 413.40(a)(3)

In addition to the proposed conforming changes discussed in X.B.2.m.(1). of the preamble of this proposed rule, we are proposing a technical correction and a revision to paragraph (a)(3) of § 413.40. We are proposing to revise the regulation text that references heart, kidney, and liver acquisition costs to read organ acquisition costs as specified in part 413 subpart L so that the language reflects all solid organs for which Medicare covers organ acquisition costs and directs readers to the organ acquisition cost in part 413.

(6) Proposed Regulatory Changes to Section 413.200

We are proposing to remove the regulation found at 42 CFR 413.200 entitled Payment of Independent organ procurement organizations and histocompatibility laboratories. We are proposing to add § 413.400 to contain revised text from § 413.200(b), and to add § 413.420 to contain the remaining regulation text from § 413.200 (a) and (c) through (g), along with a revised title, so that the content of § 413.200, with revisions, is located with other regulations specific to organ acquisition in part 413, new subpart L. We are proposing to make a technical correction or revisions to two of the three definitions found in § 413.200(b), as described in section X.B.2.a.(2). of the preamble of this proposed rule. We are proposing to add these definitions to proposed § 413.400, as described in section X.B.2.a.(2). of the preamble of this proposed rule.

We are proposing to relocate and revise the regulation title and regulation text currently existing in § 413.200 in paragraphs (a), and (c) through (g), by adding § 413.420, entitled ''Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs'' and by adding paragraphs (a), and (c) through (g) with the text from those same paragraphs in § 413.200. We are proposing to make conforming changes to the regulation text in § 413.420(a) and (c) through (g) to distinguish independent OPOs (IOPOs) from all OPOs where appropriate, in accordance with the proposed definition of IOPO in § 413.400. We also are proposing to add paragraph (b) to § 413.420 with a subtitle of ''Definitions'', to provide a cross-reference to the definitions in § 413.400 of new subpart L. Therefore, the proposed new § 413.420 would maintain the same paragraph structure as the existing § 413.200. Finally, we are proposing minor revisions to clarify the regulation text, including changing language from passive to active tense, changing verbs from future tense to present tense, and editing to improve readability.

3. Solicitation of Comments Regarding Surgeon Fees for Cadaveric Donor Excisions

Since 1987, we have limited the amount an OPO may reimburse a physician for cadaveric kidney donor retrieval services. Chapters 27 and 31 of the PRM limit the physician payment for cadaveric kidney retrieval to $1,250 per donor (one or two kidneys). The history behind the limitation on physician payment may be based on a July 1974 $400 physician services limitation on excising kidneys in community hospitals that do not participate in Medicare, which was noted in a Part A Intermediary Letter (IL No. 74–23, July 1974); it may also be based in part on the 1983 median cost paid by OPOs for surgical excision of cadaveric kidneys, which was approximately $800.[1518] Although the payments made to physicians for organ retrieval services associated with other types of organ transplants have increased, cadaveric kidney retrieval rates have remained capped at $1,250. We have received several requests to change the amount we pay for cadaveric kidney retrievals. In the CY 2009 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009 (hereafter, Physician's Fee) proposed rule (73 FR 38580 and 38581), we solicited public comments and data that are reflective of organ retrieval service costs for all types of organs. At that time, we did not have data upon which

[1518] Organ Transplants: Hearings before the Subcommittee on Investigations and Oversight, of the House Committee on Science and Technology. 98th Cong. 43 (1983) (testimony of Carolyne K. Davis, Ph.D., Administrator, Health Care Financing Administration).

to base a change in payment. We stated that we may use this information to determine the extent to which a recalculation of the payment for cadaveric organ retrieval services performed by a physician is warranted and to inform any future rulemaking on this subject. We received four timely public comments in response to our request for information and data for use in updating the organ retrieval physician payment amount included in organ acquisition costs, which were discussed in detail in the CY 2009 Physicians Fee Schedule final rule (73 FR 69864). However, we did not receive any data that would be useful in evaluating the appropriateness of the $1,250 per donor surgeon fee limit for cadaveric kidney retrievals.

For this proposed rule, we used 2017 cost report data from 48 OPOs to calculate a surgeon fee cost per local kidney for each provider, by dividing the kidney surgeon fee costs reported on Worksheet A–2, line 13, column 3 of the MCR by the number of local kidneys reported on Worksheet S–1, Part 1, Line 1, column 1 of the MCR. Excluding three providers with extremely low surgeon fees per local kidney (ranging from $0 to $231), the average surgeon fee cost per local kidney was $745. These provider-reported data suggest that the $1,250 limit on surgeon fees for cadaveric donor kidney retrievals is sufficient and allows for some higher cost excisions. However, we have received comments suggesting that this limit needs to be reconsidered.

While we are not proposing to change the physician payment limit for cadaveric kidney retrieval in this proposed rule, we are soliciting information on the physician effort and resources required to procure a cadaveric kidney for transplantation. Specifically, we are soliciting data or other information on surgical time, dry runs (number and percentage of retrievals in which an organ is not recovered), travel and wait times, as well as the incremental time required for extended criteria donors and donors after cardiac death. Additionally, we are soliciting resource information to determine the difference in procuring one kidney or a pair of kidneys from a single donor. The comments we receive may inform development of future proposals related to surgeon fee payment for organ retrieval from cadaveric donors. Any possible future rulemaking would provide for notice and public comment.

C. Medicare Shared Savings Program—Proposed Policy Changes (§ 425.600)

1. Background

The Medicare Shared Savings Program (Shared Savings Program) was established under section 1899 of the Act to facilitate coordination and cooperation among providers and suppliers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an accountable care organization (ACO). The regulations implementing the Shared Savings Program are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802)). A complete list of all of the statutes and regulations pertaining to the Shared Savings Program is located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-statutes-and-regulations*.

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** titled ''Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017'' (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models (in which they may share in savings and are accountable for repaying shared losses); new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the December 2018 final rule, we established the BASIC track in a new provision at § 425.605. The BASIC track includes an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (using a loss recoupment limit calculated based on ACO participant revenue and capped at a percentage of the ACO's updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as the glide path (83 FR 67841). The glide path includes five levels: A one-sided model available only for the first 2 consecutive performance years (PYs) of an ACO's initial 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in PYs 3 through 5 of the agreement period (Levels C, D, and E). Eligible ACOs that have previously participated in Track 1 of the Shared Savings Program may enter the glide path at Level B. ACOs are automatically advanced along the progression of risk/reward levels at the start of each performance year, over the course of a 5-year agreement period, unless the ACO elects to advance more quickly, until ACOs reach the BASIC track's maximum level of risk/reward (Level E) (83 FR 67844). Level E qualifies as an Advanced Alternative Payment Model and clinicians in ACOs participating in Level E of the BASIC track may qualify for APM incentive payments under the Quality Payment Program if they meet the criteria to become Qualifying APM Participants (QPs). For ACOs that entered the BASIC track's glide path for an agreement period beginning on July 1, 2019, the progression through the levels of risk and potential reward spans 6 performance years, including the ACO's first performance year from July 1, 2019, through December 31, 2019; these ACOs were not automatically advanced to the next risk/reward level at the start of PY 2020 (for more information, see §§ 425.200(b)(4)(ii) and (c)(3) and 425.600(a)(4)(i)(B)(2)(i)).

As of January 1, 2021, there are 477 Shared Savings Program ACOs serving approximately 10.7 million Medicare FFS beneficiaries across the country: 41 percent of ACOs (195 of 477) are currently participating under two-sided shared savings and shared losses models; and 194 ACOs are participating under the BASIC track's glide path, including 163 ACOs in one-sided Levels A and B and 31 ACOs in two-sided Levels C and D. For PY 2021, 6 ACOs elected to advance more quickly along the glide path to Level E for a total of 69 ACOs currently participating under Level E of the BASIC track.

The COVID–19 pandemic and the resulting ongoing public health emergency (PHE), as defined in 42 CFR 400.200, have continued to create a lack of predictability for many ACOs regarding the impact of utilization changes on beneficiary assignment and performance year expenditures. The PHE has disrupted population health activities as clinicians, care coordinators

and financial and other resources are diverted to address immediate needs, including acute care and vaccine delivery. The lack of predictability and disrupted population health activities created concern for some ACOs regarding the impact on their Shared Savings Program performance and the potential for shared losses. In the interim final rule with comment period (IFC) that appeared in the May 8, 2020 **Federal Register** (85 FR 27575 and 27576) (hereinafter referred to as the ''May 2020 COVID–19 IFC''), we modified the Shared Savings Program policy of automatic advancement along the glide path to allow BASIC track ACOs participating in the glide path the option to forgo the first automatic advancement along the glide path's increasing levels of risk and potential reward. We subsequently finalized the modified policy without change in the CY 2021 Physician Fee Schedule (PFS) final rule (85 FR 84767 through 84769). Under the terms of the current regulations, BASIC track ACOs that elected this option for performance year 2021 will be automatically advanced for performance year 2022 to the level at which they would have otherwise participated under automatic advancement if they had not elected the option. Seventy-four percent of eligible BASIC track ACOs (148 of 201) elected the 1-year ''freeze'' for PY 2021. Another 18 BASIC track ACOs elected to take on risk, by either automatically transitioning to Level C or by advancing more quickly along the glide path.

2. Proposal Regarding Basic Track Risk ''Freeze'' Option

Due to the continued PHE for COVID–19, ACOs and other stakeholders have requested that the exception that allowed ACOs in the BASIC track to opt for a risk ''freeze'' for PY 2021 be continued for PY 2022. While the PHE for COVID–19 remains ongoing, new considerations and challenges that impact ACO operations and expenditures continue to emerge: (1) The effects of cancelling or delaying services during the PHE, including the expectation that beneficiaries who may have gone without routine and acute care during the PHE will need increased care; (2) the emergence of new variants and mutations of the existing variants of the coronavirus that causes COVID–19; and (3) the resources involved in vaccinating the Medicare population. Given the inability of ACOs to anticipate the extent to which these issues may impact expenditures during PY 2022 and effectively prepare for these issues, we believe providing additional flexibilities to address the uncertainty produced by the ongoing PHE for COVID–19 is essential to encourage ACOs to continue participating in the Shared Savings Program during the ongoing PHE for COVID–19.

As noted previously, in the May 2020 COVID–19 IFC, we adopted a new provision at § 425.600(a)(4)(i)(B)(2)(iii) to provide the opportunity for ACOs participating in the BASIC track's glide path to maintain their level of participation for PY 2021 and not automatically progress to a higher level along the glide path. For PY 2022, the ACOs that voluntarily elected to ''freeze'' their participation level in accordance with § 425.600(a)(4)(i)(B)(2)(iii) are currently required to progress to the level of participation they would have been automatically advanced to, absent the election to maintain their participation level for PY 2021. For example, if an ACO in Level B of the BASIC track in PY 2020 elected to maintain its participation in Level B for PY 2021, the ACO will be automatically transitioned to Level D for PY 2022. Level D of the BASIC track is a two-sided model with a 50-percent sharing rate and 30-percent loss sharing rate, not to exceed 4 percent of ACO participant revenue capped at 2 percent of the ACO's updated benchmark.

Stakeholders have continued to express concern that as a result of the unpredictable circumstances of the PHE and the sustained impacts of the COVID–19 pandemic during PY 2021, some ACOs may terminate their participation in the program if they are required to automatically transition to downside risk or a higher level of downside risk for PY 2022. Specifically, stakeholders have requested that we allow a second ''freeze'' to permit ACOs participating in the BASIC track's glide path to opt out of automatic advancement from their current level of participation for PY 2022.

As detailed in the May 2020 COVID–19 IFC (85 FR 27576), per § 425.204(f)(3)(iii), an ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate, or is automatically transitioned to a two-sided model of the BASIC track, including Level C, Level D or Level E. We believe that it would be appropriate to provide the flexibility to ACOs, particularly those that would otherwise automatically transition to Level C or D of the BASIC track for PY 2022, to delay transitioning to two-sided risk, thus delaying the requirement to establish a repayment mechanism prior to the start of PY 2022. This flexibility would allow these ACOs the option to put financial resources that might otherwise be used to establish a repayment mechanism towards continuing to care for their beneficiaries during the ongoing pandemic. Currently, the Shared Savings Program has 163 ACOs participating under Level A or Level B of the BASIC track that are scheduled to automatically advance to Level C or Level D on January 1, 2022.

We are also concerned that the PHE for COVID–19 has made expenditures and utilization more difficult to predict and that ACOs may be more risk-averse as patient care patterns have been altered by the pandemic. ACOs cannot know the full impact that the PHE for COVID–19 and the related changes in health care utilization will have on their total expenditures or their assigned beneficiary population. In addition, the duration of the PHE for COVID–19 remains uncertain, and it is unclear whether the PHE will extend into 2022, such that shared losses owed by ACOs participating under two-sided payment models would be mitigated under the Shared Savings Program's extreme and uncontrollable circumstances policy. Therefore, we propose that ACOs participating in the BASIC track's glide path may elect to maintain their current level of risk under the BASIC track for PY 2022. Specifically, we propose that before the automatic advancement for PY 2022, an applicable ACO may elect to remain in the same level of the BASIC track's glide path in which it participated during PY 2021. For PY 2023, an ACO that elects this advancement deferral option would be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if it had advanced automatically to the required level for PY 2022 (unless the ACO elects to advance more quickly before the start of PY 2023). For example, if an ACO that participated in the BASIC track Level A for PY 2020, then automatically advanced to Level B in PY 2021, elects to maintain its current level of participation for PY 2022, it would participate under Level B for PY 2022 and then would automatically advance to Level D for PY 2023. The ACO could also elect to advance more quickly by opting to move to Level E instead of Level D for PY 2023, in which case the ACO would participate under Level E for the remainder of its agreement period. In contrast, if an ACO that participated in the BASIC track Level B for PY 2020 elected to maintain its participation at

Level B for PY 2021, but does not elect to maintain its participation under Level B for PY 2022, the ACO would automatically advance to Level D for PY 2023, unless it chooses to advance more quickly.

Under this proposal, an ACO that elects to freeze its participation level for both PY 2021 and PY 2022 would be automatically advanced for PY 2023 to the level of the BASIC track's glide path in which it would have participated during PY 2023, absent both of its elections to freeze. For example, if an ACO participating in the BASIC track, Level B, in PY 2020 elected to maintain its current level of participation for PY 2021, and then chose again to maintain its current level of participation for PY 2022, it would continue to participate under Level B in both PY 2021 and PY 2022, before automatically advancing to Level E for PY 2023. In this example, the ACO would participate under Level E for the remainder of its agreement period. We have provided the following table to illustrate the potential scenarios for ACOs that elect to maintain their current level of risk for PY 2021 or PY 2022 or both. This chart is intended only to address ACOs that may want to elect to ''freeze'' for PY 2022 and does not address other participation options, such as the exception that allows certain ACOs to elect to remain in Level B for an additional performance year, and then automatically advance to Level E for the final 2 participation years of their agreement as specified at § 425.600(a)(4)(i)(B)(2)(ii).

BASIC TRACK'S GLIDE PATH "FREEZE" SCENARIOS			
PY 2020	**PY 2021**	**PY 2022**	**PY 2023**
Level A	Maintained at Level A	Maintain at Level A	Progress to Level D
		Progress to Level C	
	Progressed to Level B	Maintain at Level B	
		Progress to Level C	
Level B	Maintained at Level B	Maintain at Level B	Progress to Level E
		Progress to Level D	
	Progressed to Level C	Maintain at Level C	
		Progress to Level D	
Level C	Maintained at Level C	Maintain at Level C	Progress/Maintain Level E

BASIC TRACK'S GLIDE PATH "FREEZE" SCENARIOS			
PY 2020	**PY 2021**	**PY 2022**	**PY 2023**
		Progress to Level E	
	Progressed to Level D	Maintain at Level D	
		Progress to Level E	
Level D	Maintained at Level D	Maintain at Level D	Progress/Maintain Level E
		Progress to Level E	
	Progressed to Level E	Maintain Level E	

We propose that the ACO's voluntary election to maintain its participation level for PY 2022 must be made in the form and manner and by a deadline established by CMS, and an ACO executive who has the authority to legally bind the ACO must certify the election. We recognize that the annual application and change request cycle will begin before the FY 2022 IPPS/LTCH PPS rulemaking is finalized. Accordingly, we will give ACOs the

opportunity during the change request cycle to indicate whether they are interested in maintaining their participation at Level A or Level B under this proposed policy, should it be finalized. ACOs expressing such an interest would not be required to submit a repayment mechanism at that time. In the event this proposed policy is not finalized in the FY 2022 IPPS/LTCH PPS final rule, ACOs that are required under § 425.600(a)(4)(i)(B)(2)(iii) to advance from Level A or Level B to a two-sided risk model for PY 2022 would have a limited opportunity to submit a repayment mechanism, resolve any deficiencies, and have it approved in time for the start of the performance year. ACOs that fail to establish a repayment mechanism that complies with the requirements of § 425.204(f) by the deadline specified by CMS would be terminated as required under § 425.600(a)(4)(i)(B)(*3*).

We propose to redesignate § 425.600(a)(4)(i)(B)(*2)(iv*) as § 425.600(a)(4)(i)(B)(*2)(v*). Additionally, we propose to add a new § 425.600(a)(4)(i)(B)(*2*)(*iv*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2022. We intend to continue to monitor the PHE for COVID–19 and assess its impact on the Shared Savings Program. We will address any additional flexibilities that may be warranted as a result of the ongoing PHE through future notice and comment rulemaking.

Lastly, in the May 2020 COVID–19 IFC (85 FR 27625), we revised the regulations at § 425.600 to allow BASIC track ACOs to maintain their participation level for PY 2021 by redesignating paragraph (a)(4)(i)(B)(*2*)(*iii*) as paragraph (a)(4)(i)(B)(*2*)(*iv*) and adding a new paragraph (a)(4)(i)(B)(*2*)(*iii*). In making this amendment, we inadvertently omitted the revision to the cross-reference in paragraph (a)(4)(i)(B)(*3*). In this proposed rule, we are proposing to make further revisions to § 425.600(a)(4)(i)(B)(*2*), which would also affect the cross-reference in paragraph (a)(4)(i)(B)(*3*). Therefore, we propose to revise § 425.600(a)(4)(i)(B)(*3*) to remove the reference to paragraph (a)(4)(i)(B)(*2*)(*iii*) and replace it with a reference to paragraph (a)(4)(i)(B)(*2*)(*v*).

XI. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2021''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2022 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at: *http://www.medpac.gov*.

XII. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* Following is a listing of the IPPS-related data files that are available.

As discussed in section II.A. of the preamble of this proposed rule, we are proposing to use the FY 2019 data for the FY 2022 IPPS and LTCH PPS ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. As discussed in section I.O. of Appendix A of this proposed rule, as an alternative to our proposed approach, we considered using the FY 2020 data we would ordinarily use in the FY 2022 IPPS and LTCH PPS ratesetting. In order to facilitate comments on this alternative approach, which we may consider finalizing for FY 2022 based on consideration of comments received, we are making available the FY 2020 MedPAR file and the FY 2019 HCRIS file that we would ordinarily have provided in conjunction with this proposed rule, as well as other proposed rule supporting data files based on the use of the FY 2020 data, including the IPPS and LTCH PPS Impact Files, the AOR/BOR File, the Case Mix Index File, and the Standardizing File. We refer the reader to section I.O. of Appendix A of this proposed rule for a discussion of the files that we are making available with regard to our alternative approach of using the FY 2020 data that we would ordinarily use in the FY 2022 IPPS and LTCH PPS ratesetting.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2018 Medicare cost reports used to create the proposed FY 2022 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*. Periods Available: FY 2007 through FY 2022 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2019 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*. Period Available: FY 2022 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2022 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule. Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*. Periods Available: FY 2005 through FY 2022.

5. FY 2022 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core Based Statistical Areas (CBSAs).

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2022 proposed rule home page or the FY 2022 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html*.

Period Available: FY 2022 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: internet at: *https://www.cms.gov/Research-Statistics-Dataand-Systems/Downloadable-Public-UseFiles/Cost-Reports/Cost-Reports-byFiscal-Year.html*.

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text.html*.

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/Acute-InpatientFiles-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2022.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/Acute-InpatientFiles-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2022 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/Historical-ImpactFiles-for-FY-1994-through-Present.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1994 through FY 2022 IPPS Update.

11. AOR/BOR File

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR file are ''Before Outliers Removed'' and the AOR file is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.) Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/Acute-InpatientFiles-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2022 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the CoreBased Statistical Area (CBSA). The file supports the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2022 proposed rule home page or the FY 2022 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html*.

Period Available: FY 2022 IPPS Update.

13. MS–DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-*

Feefor-Service-Payment/AcuteInpatientPPS/index.html (on the navigation panel on the left side of the page, click on the FY 2022 proposed rule home page or the FY 2022 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html*.

Period Available: FY 2022 IPPS Update

14. Hospital Readmissions Reduction Program Supplemental File

Updated data are not available at this time. Therefore, we refer readers to the FY 2021 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2022 IPPS/LTCH PPS proposed rule supplemental file.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2022 proposed rule home page or the FY 2022 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html*.

Period Available: FY 2022 IPPS Update.

15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2022. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2022 proposed rule home page or the FY 2022 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/AcuteInpatientPPS/AcuteInpatient-Files-for-Download.html*.

Period Available: FY 2022 IPPS Update.

16. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. (As discussed in section II.G. of this proposed rule, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.) Two versions of this file are created each year to support rulemaking. (We note that the information in this file was previously provided in Table 10 of the annual IPPS proposed and final rules (83 FR 41739).)

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-InpatientFiles-for-Download.html*.

Periods Available: For FY 2022 and FY 2023 applications.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs Relating to the Hospital Readmissions Reduction Program

In section V.G. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital Readmissions Reduction Program. In this proposed rule, we are not proposing to remove or adopt any new measures into the Hospital Readmissions Reduction Program for FY 2022. All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures. We believe that continuing to use these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

In section V.G.6. of the preamble of this proposed rule, we discuss our proposal to suppress the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization measure (NQF #0506) due to the significant impact of the COVID–19 Public Health Emergency on this measure, for FY 2023. However, we believe that the proposed updates to these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

3. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.H. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, Medicare Spending per Beneficiary (MSPB), and the five hospital-acquired infection (HAI) measures for the FY 2022 program year. We are also proposing to remove the CMS PSI 90 measure beginning with the FY 2023 program year and suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) measure for the FY 2023 program year. Because the FY 2022 and FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, we do not anticipate any change in burden associated with this proposed rule.

4. ICRs for the Hospital Acquired Condition (HAC) Reduction Program

In this proposed rule, we are not proposing to remove any measures, adopt any new measures into the HAC Reduction Program, or update our validation procedures. The HAC Reduction Program has adopted six measures. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates or reduces any burden for hospitals because it is collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes. We note the burden associated with collecting and submitting data for the HAI measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, MRSA bacteremia, and CDI) via the NHSN system is captured under a separate OMB control number, 0920–0666 (expiration November 30, 2021), and therefore will not impact our burden estimates.

5. ICRs Regarding the Implementation of Section 126 of the Consolidated Appropriations Act—Distribution of Additional Residency Positions

As discussed in section V.J.2.a. of the preamble of this proposed rule, teaching hospitals would be able to submit electronic applications to CMS for resident slot increase requests. The burden associated with these requests will be discussed in a forthcoming information collection request, which is currently under development. However, upon completion of the ICR, we will publish the required 60-day and 30-day notices to solicit public comments in accordance with the requirements of the PRA.

6. ICR for Proposed Repeal of Market-Based MS–DRG Relative Weight Data Collection

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021 (85 FR 58873 through 58892); this data collection requirement is specified in 42 CFR 413.20(d)(3). We also finalized the use of this data in a new market-based methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing, beginning in FY 2024. Specifically, we finalized that we will begin using the reported median payer-specific negotiated charge by MS–DRG for MA organizations in the market-based MS–DRG relative weight methodology beginning with the relative weights calculated for FY 2024. Further instructions for the reporting of this market-based data on the Medicare cost report were discussed in the revision of the ICR currently approved under OMB control number 0938–0050, expiration date March 31, 2022 and published on November 10, 2020 (for more information we refer readers to (*https://www.federalregister.gov/documents/2020/11/10/2020-24948/agency-information-collection-activities-proposed-collection-comment-request* and *https://www.cms.gov/regulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-2552-10*).

In the FY 2021 IPPS/LTCH PPS final rule we estimated an average annual burden per hospital of 20 hours (5 hours for recordkeeping and 15 hours for reporting) for completing the Worksheet S–12 and complying with 42 CFR 413.20(d)(3). The 20 hours per hospital to complete the Worksheet S–12 includes 5 hours for recordkeeping, including bookkeeping, accounting and auditing clerk tasks. The remaining 15 hours for reporting include accounting and audit professionals' activities. We estimated that 3,189 hospitals would be required to comply with this market-based data collection requirement. This equated to an estimated total annual burden hours as follows: 3,189 hospitals times 20 hours per hospital equals 63,780 annual burden hours.[1519] We calculated a total annual cost of $1,353.40 per hospital, or $4,315,993 across all hospitals. We refer readers to 85 FR 59015 for further information.

Section V.L. of the preamble of this proposed rule discusses the proposed repeal of the market-based MS–DRG relative weight data collection and market-based methodology for calculating MS–DRG relative weights. If we were to finalize our proposal to repeal the market-based data collection and relative weight methodology, we estimate a reduction of 63,780 annual burden hours for hospitals, which equals a reduction of $4,315,993 across all hospitals.

7. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 1,572,443 hours of burden and approximately $61 million under OMB control number 0938–1022, accounting for information collection burden experienced by approximately 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2023 payment determination. In this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938–1022 (expiration date December 31, 2022) for IPPS hospitals due to the proposals in this proposed rule.

We refer readers to section IX.C. for more detail on our proposals. In this year's proposed rule, we are making several proposals which, if finalized, would affect the information collection burden associated with the Hospital IQR Program. We are proposing to adopt the: (1) Maternal Morbidity Structural Measure beginning with a shortened reporting period from October 1 through December 31, 2021 (affecting the FY 2023 payment determination), followed by annual reporting periods for subsequent years; and (2) Hybrid Hospital-Wide All-Risk Standardized Mortality measure with Claims and Electronic Health Record Data (Hybrid HWM measure) beginning with a one-year voluntary reporting period (July 1, 2022 through June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023 through June 30, 2024 reporting period/FY 2026 payment determination. We expect these proposals will affect our collection of information burden estimates. Details on these policies as well as the expected burden changes are discussed further in this section of this proposed rule.

We are also proposing several updates which would not affect the information collection burden associated with the Hospital IQR Program. In section IX.C. of the preamble to this proposed rule, we are proposing to: (1) Adopt the Hospital Harm—Severe Hyperglycemia electronic clinical quality measure (eCQM) beginning with the CY 2023 reporting period/FY 2025 payment determination; (2) adopt the Hospital Harm—Severe Hypoglycemia eCQM beginning with the CY 2023 reporting period/FY 2025 payment determination; (3) adopt the COVID–19 Vaccination Coverage Among HCP measure beginning with a shortened reporting period from October 1 to December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination; (4) remove the Death Rate among

[1519] This estimate was finalized in the FY 2021 IPPS/LTCH PPS final rule. These estimates were based on the most recent data, available at the time of the final rule, from the System for Tracking Audit and Reimbursement, an internal CMS data system maintained by the Office of Financial Management (OFM).

Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) claims-based measure beginning with the FY 2023 payment determination; (5) remove the Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) remove the Exclusive Breast Milk Feeding (PC–05) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) remove the Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (8) remove the Discharged on Statin Medication (STK–06) eCQM measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (9) revise the Program's regulations at 42 CFR 412.140(a)(2) by replacing the term ''QualityNet Administrator'' with the term ''QualityNet security official'' and 42 CFR 412.140(e)(2)(iii) by replacing the term ''QualityNet system administrator'' with the term ''QualityNet security official''; (10) revise the Program's regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to remove references to ''QualityNet.org'' and replacing it with ''QualityNet website''; (11) require the use of the 2015 Edition Cures Update for certification criteria beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years for both eCQMs and hybrid measures; and (12) extend the effects of educational reviews for fourth quarter data such that if an error is identified during the education review process for fourth quarter data, we would use the corrected quarterly score to compute the final confidence interval used for payment determination beginning with validations affecting the FY 2024 payment determination. As discussed further in this proposed rule, we do not expect these proposals to affect our information collection burden estimates.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 59008), we estimated that reporting measures for the Hospital IQR Program could be accomplished by staff with a median hourly wage of $19.40 per hour. We note that since then, more recent wage data have become available, and we are updating the wage rate used in these calculations in this proposed rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $20.50 per hour for a medical records and health information technician professional.[1520] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($20.50 × 2 = $41.00) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $41.00 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

b. Information Collection Burden Estimate for the Proposed Maternal Morbidity Structural Measure

In section IX.C.5.a. of the preamble of this proposed rule, we are proposing to adopt the Maternal Morbidity Structural Measure beginning with the CY 2021 reporting period/FY 2023 payment determination. The shortened data submission period for the Maternal Morbidity Structural Measure would run from October 1 through December 31, 2021, followed by annual reporting periods for subsequent years. Reporting on the Maternal Morbidity Structural Measure would involve each hospital responding to a single question using a web-based tool available via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System) with one of the following response options: (A) ''Yes''; (B) ''No''; or (C) ''N/A (our hospital does not provide inpatient labor/delivery care).''

If our proposal is finalized, hospitals would be required to submit the response on an annual basis during the submission period. We estimate the information collection burden associated with this proposed structural measure to be no more than five minutes per hospital per year, as it involves responding to a single question one time per year for a given reporting period. Using the estimate of 5 minutes (or 0.083 hours) per hospital per year, and the updated wage estimate as described previously, we estimate that this policy will result in a total annual burden increase of 275 hours across all IPPS hospitals (0.083 hours × 3,300 IPPS hospitals) at a cost of $11,275 (275 hours × $41).

[1520] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on February 18, 2021; available at: *https://www.bls.gov/oes/2019/may/oes292098.htm.*

c. Information Collection Burden Estimate for the Proposed Voluntary Reporting Period and Subsequent Required Submission of the Hybrid Hospital-Wide Mortality Measure With Claims and Electronic Health Record Data

In section IX.C.5.b. of the preamble of this proposed rule, we are proposing to establish a voluntary reporting period for the Hybrid Hospital-Wide Mortality Measure with Claims and Electronic Health Record Data (NQF #3502) (Hybrid HWM measure). The voluntary reporting period would run from July 1, 2022 through June 30, 2023. We also are proposing to require reporting of the Hybrid HWM measure beginning with the reporting period which would run from July 1, 2023 through June 30, 2024 affecting the FY 2026 payment determination and for subsequent years.

As a hybrid measure, this measure uses both claims-based data and EHR data, specifically, a set of core clinical data elements consisting of vital signs and laboratory test information and patient linking variables collected from hospitals' EHR systems. We do not expect any additional burden to hospitals to report the claims-based portion of this measure because these data are already reported to the Medicare program for payment purposes.

However, we do expect that hospitals would experience burden in reporting the EHR data. To report the EHR data, hospitals would use the same submission process as finalized in the FY 2020 IPPS/LTCH PPS final rule for reporting the Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and EHR Data (NQF #2879) (Hybrid HWR measure) (84 FR 42505 through 42508). We expect the burden associated with reporting of the Hybrid HWM measure to be similar to our estimates for reporting the Hybrid HWR measure, that is, 10 minutes per measure, per quarter. Therefore, using the estimate of 10 minutes per measure per quarter (10 minutes × one measure × four quarters = 40 minutes), we estimate that our proposal will result in a burden increase of 40 minutes (0.67 hours) per hospital per year.

Beginning with the voluntary reporting period, which runs from July 1, 2022 through June 30, 2023, we estimate an annual burden increase of 2,200 hours across participating IPPS hospitals (0.67 hours × 3,300 IPPS hospitals). Using the updated wage estimate, as previously described, we estimate this to represent a cost increase of $90,200 across IPPS hospitals ($41 × 2,200 hours). If our proposal to adopt

the Hybrid HWM measure is finalized, we will encourage all hospitals to submit data for the Hybrid HWM measure during the voluntary reporting period. For that reason, our burden estimates assume that all hospitals would participate during the voluntary reporting period (July 1, 2022 through June 30, 2023) as well as for the required reporting period (July 1, 2023 through June 30, 2024) and subsequent reporting periods for which public reporting would begin. Due to the voluntary reporting period beginning in the third quarter of the CY 2022 Reporting Period/FY 2024 Payment Determination, the total burden of for the first year assumes only two quarters of reporting and is estimated to be 1,100 hours (0.33 hours × 3,300 IPPS hospitals) at a cost of $45,100 ($41 × 1,100 hours). Beginning with the CY 2023 Reporting Period/FY 2025 Payment Determination, the total burden estimate will be based on four quarters of reporting.

d. Information Collection Burden Estimate for the Proposed Adoption of Two Hospital Harm eCQMs Beginning With the CY 2022 Reporting Period/FY 2024 Payment Determination and Removal of Four eCQMs Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.C.5.d. of the preamble of this proposed rule, we are proposing to adopt two eCQMs beginning with the CY 2023 reporting period/FY 2025 payment determination: (1) Hospital Harm—Severe Hyperglycemia eCQM; and (2) Hospital Harm—Severe Hypoglycemia eCQM. Also, in section IX.C.6. of this proposed rule, we are proposing to remove four eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination: (1) Admit Decision Time to ED Departure Time for Admitted Patients (ED–2); (2) Exclusive Breast Milk Feeding (PC–05); (3) Anticoagulation Therapy for Atrial Fibrillation/Flutter (STK–03); and (4) Discharged on Statin Medication (STK–05) eCQMs. We do not believe that our proposals to add two eCQMs and remove four eCQMS from the eCQM measure set will affect the information collection burden of submitting eCQMs under the Hospital IQR Program. Current Hospital IQR Program policy requires hospitals to select four eCQMs from the eCQM measure set on which to report (84 FR 42503 through 4250). In other words, while these proposals would result in new eCQMs being added to and some eCQMs being removed from the eCQM measure set, hospitals will not be required to report more than a total of four eCQMs as is currently required (84 FR 42603).

Specifically, we finalized in the FY 2020 IPPS/LTCH PPS final rule that, for the CY 2021 reporting period/FY 2023 payment determination, hospitals are required to submit data for four self-selected eCQMs each year (84 FR 42503). Additionally, for the CY 2022 reporting period/FY 2024 payment determination, hospitals are required to submit data for three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM for a total of four eCQMs (84 FR 42505). We also finalized a policy to progressively increase the number of quarters of eCQM data reported, from one quarter of data to four quarters of data over a 3-year period beginning with two quarters in the CY 2021 reporting period/FY 2023 payment determination and culminating with four quarters in the CY 2023 reporting period/FY 2025 payment determination (85 FR 59008 through 59009). The new eCQMs proposed in this proposed rule would update the available eCQMs in the eCQM measure set from which hospitals may choose to report to satisfy these requirements. Therefore, we do not expect that our proposals to adopt or remove these measures would impact our information collection burden estimates. However, we refer readers to section I.K. of Appendix A of this proposed rule for a discussion of the potential costs associated with the implementation and removal of eCQMs which are not strictly related to information collection burden.

e. Information Collection Burden Estimate for the Proposed Removal of the Death Rate Among Surgical Inpatients With Serious Treatable Complications (CMS PSI–04) Claims-Based Measure Beginning With the FY 2023 Payment Determination

In section IX.C.6.a. of the preamble of this proposed rule, we are proposing to remove the Death Rate Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) claims-based measure beginning with the CY 2021 reporting period/FY 2023 payment determination. Because PSI–04 is calculated using data that are already reported to the Medicare program for payment purposes, we do not anticipate that removing this measure will decrease our previously finalized burden estimates.

f. Information Collection Burden Estimate for the Proposed Adoption of the COVID–19 HCP Vaccination Measure Beginning With an Interim Reporting Period in CY 2021

In section IX.C.5.c. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination Measure beginning with a shortened reporting period from October 1 to December 31, 2021, affecting the CY 2021 reporting period/FY 2023 payment determination followed by quarterly reporting periods for the FY 2024 payment determination and for subsequent years. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA (OMB control number 0920–1317) because the agency has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1521] As such, the proposed measure would not impose any additional information collection burden for IPPS hospitals for the duration of the PHE. Although the burden associated with the COVID–19 Vaccination Among HCP measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666 due to the NCVIA waiver, the cost and burden information is included in the Regulatory Impact Analysis section (Appendix A, section I.K.) of this rule. Upon receiving comment, we will work with CDC to ensure that this burden is accounted for in an updated PRA under OMB control number 0920–1317.

g. Information Collection Burden Estimates for the Proposals To Adopt the 2015 Edition Cures Update Criteria for Certified EHR Technology (CEHRT) Beginning With the CY 2023 Reporting Period/FY 2025 Payment Determination for eCQMs and Hybrid Measures

In sections IX.C.8.e.2.(a). and IX.C.8.f.2.(b). of the preamble of this proposed rule, we are proposing to require hospitals use the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years. Under this proposal, hospitals would no longer be able to use the 2015 Edition

[1521] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

CEHRT criteria to submit data for the Hospital IQR Program data submission requirements for eCQMs or hybrid measures beginning with the CY 2023 reporting period/FY 2025 payment determination. We do not expect that these proposals, if finalized, would affect our information collection burden estimates because this policy does not require hospitals to submit new data to CMS (83 FR 41692). With respect to any costs unrelated to data submission, we refer readers to section I.K. of Appendix A of this proposed rule.

h. Information Collection Burden Estimate for the Proposals To Update References and Code of Federal Regulations Text Relating to QualityNet Security Administrator

In section IX.C.8.c.2. of the preamble of this proposed rule, we are proposing to use the term ''QualityNet security official'' instead of ''QualityNet Administrator.'' Specifically, we are proposing to revise existing § 412.140(a)(2) by replacing ''QualityNet Administrator'' with ''QualityNet security official'' and § 412.140(e)(2)(iii) by replacing ''QualityNet system administrator'' with ''QualityNet security official.'' We expect that our proposals will not yield a change in burden for the hospitals participating in the Hospital IQR Program since the changes only seek to refine regulatory text.

i. Information Collection Burden Estimate for the Proposal To Update References to the QualityNet Website in the Hospital IQR Program Regulation Text

In section IX.C.8.c.(1). of the preamble of this proposed rule, we are proposing to update the references to the QualityNet website from ''*QualityNet.org*'' to ''the QualityNet website'' in the Hospital IQR Program regulation text. Specifically, we are proposing to revise existing § 412.140(a)(1) and (c) to remove references to ''*QualityNet.org*'' and replace with ''QualityNet website.'' We expect that our proposals will not yield a change in burden for the hospitals participating in the Hospital IQR Program since the changes only seek to refine regulatory text.

j. Information Collection Burden Estimate for the Proposal To Extend the Effects of the Educational Review Process for Chart-Abstracted Measures for the FY 2024 Payment Determination and Subsequent Years

In section IX.C.9.b.(1).(b). of the preamble, we are proposing extend the educational review policy to use the corrected quarterly score identified through an educational review to compute the final confidence interval for all 4 quarters of validation for chart-abstracted measures. We expect that our proposal will not yield a change in burden as it does not affect the requirements for data submission for hospitals, but only modifies how CMS uses the data already being submitted.

k. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate that the policies promulgated in this proposed rule will result in an increase of 2,475 hours annually for 3,300 IPPS hospitals across a 4-year period from the CY 2022 reporting period/FY 2024 payment determination through the CY 2025 reporting period/FY 2027 payment determination. The total cost increase related to this information collection is approximately $101,475 (2,475 hours × $41.00/hour) (which also reflects use of an updated hourly wage rate as previously discussed). The tables summarize the total burden changes for each respective FY payment determination compared to our currently approved information collection burden estimates (the table for the FY 2027 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022.

Summary of Hospital IQR Program Information Collection Burden Change for the CY 2022 Reporting Period/FY 2024 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2024 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of IPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across IPPS hospitals**	**Previously finalized annual burden (hours) across IPPS hospitals**	**Net difference in annual burden hours**
Add Maternal Morbidity Structural Measure	5	1	3,300	1	0.083	275	N/A	+275
Add Hybrid Hospital-Wide Mortality Measure	10	2	3,300	1	0.33	+1,100	N/A	+1,100
	Total Change in Information Collection Burden Hours: +1,375							
	Total Cost Estimate: Updated Hourly Wage ($41.00) x Change in Burden Hours (+1,375) = **+$56,375**							

Summary of Annual Hospital IQR Program Information Collection Burden Change for the CY 2023 Reporting Period/FY 2025 Payment Determination through the CY 2025/FY 2027 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2025 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of IPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across IPPS hospitals**	**Previously finalized annual burden (hours) across IPPS hospitals**	**Net difference in annual burden hours**
Add Maternal Morbidity Structural Measure	5	1	3,300	1	0.083	275	N/A	+275
Add Hybrid Hospital-Wide Mortality Measure	10	4	3,300	1	0.67	2,200	N/A	−2,200
	Total Change in Information Collection Burden Hours: +2,475							
	Total Cost Estimate: Updated Hourly Wage ($41.00) x Change in Burden Hours (+2,475) = **+$101,475**							

8. ICRs for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section IX.D. of the preamble of this final rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare reimbursement if a PCH does not participate.

In section IX.D.5. of the preamble of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021, affecting the FY 2023 program year, followed by annual reporting periods (affecting the FY 2024 program year and for subsequent years). We are proposing that PCHs would submit data on the measure through the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained by the CDC and provided free of charge to healthcare facilities, including PCHs. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1522] Although the burden as associated with the COVID–19 HCP Vaccination measure is not accounted for under the CDC package currently approved under OMB control number 920–1317 or 0920–0666, the cost and burden information is included in the Regulatory Impact Analysis section (Appendix A, section I.K.) of this rule. Upon receiving comments, we will work with CDC to ensure that this burden is accounted for in an updated PRA package prepared by the CDC under OMB control number 0920–1317.

In section IX.D.4. of the preamble of this proposed rule, we are proposing to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology (NQF #0383/PCH–15) measure beginning with the FY 2024 program year. We previously finalized in the FY 2019 IPPPS/LTCH PPS final rule that we would utilize a time estimate of 15-minutes per measure when assessing web-based and/or structural measures (83 FR 41694). As such, we estimate that the removal of this measure from the PCHQR measure set will result in a reduction of 15 minutes (0.25 hours) per PCH per year, with a total annual reduction in reporting burden across all PCHs of 2.75 hours (0.25 hours × 11 PCHs) and a total annual reduction in cost across all PCHs of $113 (2.75 hours × $41.00/hr), beginning with the FY 2024 program year.

If these policies are finalized as proposed, as previously stated, we estimate a reporting burden reduction of 0.25 hours per PCH or 2.75 total hours across 11 PCHs, beginning in the FY 2024 program year. Because the estimated reporting burden reduction per PCH is so small (0.25 hours), there is essentially no net change in the burden hours per PCH (6,889 hours [previous burden per PCH] − 0.25 hours [proposed change in burden per PCH] = 6,888.975, which rounded is 6,889 hours). We estimate our total program burden across all 11 PCHs to be 75,776 hours (75,779 [previous total burden] − 2.75 hours [proposed total change in burden]). The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $20.50 (previously $19.40),[1523] which when accounting for overhead and fringe benefits, results in an hourly wage of $41.00. Using the estimate of 75,776 burden hours across the 11 PCHs for data collection and submission of all 14 measures, we estimate a total annual labor cost of $3,106,816 (75,776 hours × $41.00 per hour) for all 11 PCHs for the FY 2024 program year. The updated burden estimates will be submitted to OMB under control number 0938–1175.

8. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

This proposed rule does not impose any new information collection requirements. However, this proposed rule does reference associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections, some of which have already received OMB approval.

As stated in section IX.E. of the preamble of this proposed rule for purposes of calculating the FY 2023 Annual Payment Update (APU), we propose that LTCHs submit data on one new quality measure: COVID–19 Vaccination Coverage among Healthcare Personnel (HCP). The data source for this quality measure is the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). LTCHs would submit the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure data to CMS through the NHSN, a web-based tool hosted by the CDC. This reporting service is provided free of charge to healthcare facilities. LTCHs currently utilize the NHSN for purposes of meeting other LTCH QRP requirements.

We believe that the burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. The burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA package currently approved under OMB control number 0920–1317 (expiration 1/31/2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986 (NCVIA).[1524] CMS has provided an estimate of the burden and cost to LTCHs, and note that the CDC will include it in a revised information collection request for 0920–1317.

Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it would take each LTCH an average of 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. We believe it would take an administrative assistant from 45 minutes up to 1 hour and 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates. To account for overhead and fringe benefits, we have doubled the hourly wage.

[1522] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[1523] Bureau of Labor Statistics, Occupational Employment and Wages. Accessed on February 12, 2021: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[1524] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

Based on the time range, it would cost each LTCH between $27.47 and $45.78 per hour each month or an average cost of $36.62 each month, and between $329.64 and $549.36 each year, or an average cost of $439.44 each year. We believe the data submission for the COVID–19 Vaccination Coverage among HCP would cause LTCHs to incur additional average burden of 12 hours per year for each LTCH and a total annual burden of 4,608 hours for all LTCHs. The estimated annual cost across all 363 LTCHs in the U.S. for the submission of the COVID–19 Vaccination Coverage among HCP measure would be between $119,659.32 and $199,417.68, and an average of $159,516.72.

We recognize that many LTCHs may also be reporting other COVID–19 data to HHS. However, we believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to assess whether LTCHs are taking steps to limit the spread of COVID–19 among HCP, reduce risk of transmission of COVID–19 within their facilities, and to help sustain the ability of LTCHs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into CDC/NHSN.

10. ICRs for the Promoting Interoperability Programs

a. Historical Background

In section IX.D. of the preamble of this proposed rule, we discuss several proposals for the Medicare Promoting Interoperability Program. OMB has currently approved 621,318 total burden hours and approximately $61 million under OMB control number 0938–1278, accounting for information collection burden experienced by approximately 3,300 eligible hospitals and CAHs (Medicare-only and dual-eligible) that attest to CMS under the Medicare Promoting Interoperability Program. The collection of information burden analysis in this proposed rule focuses on eligible hospitals and CAHs that attest to the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program for the reporting period in CY 2022, CY 2023, and CY 2024.

b. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2022

In section IX.D.3.b. of the preamble of this rule, we are proposing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) To maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from five points to 10 points for the CY 2022 EHR reporting period; (2) to modify technical specifications of the Provide Patient's Electronic Access to Their Health Information Measure to include establishing a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, effective January 1, 2022; (3) to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation, beginning in CY 2022 to the HIE objective as an optional alternative to the two existing measures; (4) to require reporting on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting); (5) that eligible hospitals and CAHs must attest to having completed an annual assessment via a SAFER Guides measure, under the Protect Patient Health Information Objective, beginning January 1, 2022; (6) to remove attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking requirement; and (7) to increase the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) in order to be considered a meaningful EHR user. We are amending our regulation text as necessary to incorporate these proposed changes.

c. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2023

In section IX.D.3.b. of the preamble of this rule, we are proposing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2023 for new and returning participants (eligible hospitals and CAHs); and (2) to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, which is in alignment with the proposals under the Hospital IQR Program. We are amending our regulation text as necessary to incorporate these proposed changes.

d. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program for CY 2024

In section IX.D.3.b. of the preamble of this rule, we are proposing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 180-day period in CY 2024 for new and returning participants (eligible hospitals and CAHs); and (2) to remove four eCQMs from the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2024, which is in alignment with the proposals under the Hospital IQR Program. We are amending our regulation text as necessary to incorporate these proposed changes.

e. Summary of Collection of Information Burden Estimates

(1) Summary of Estimates Used To Calculate the Collection of Information Burden

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated it will take an individual provider or designee approximately 10 minutes to attest to each objective and associated measure that requires a numerator and denominator to be generated. The measures that require a ''yes/no'' response will take approximately one minute to complete. We estimated that the Security Risk Analysis measure will take approximately six hours for an individual provider or designee to complete (we note this measure is still part of the program, but is not subject to performance-based scoring).

For this proposed rule, there are two proposed measure changes which would lead to an increase in overall burden to the Medicare Promoting Interoperability Program. First is the updated requirement for the Public Health and Clinical Data Exchange Objective which increases the total number of measures which must be reported from two to four. For CY 2021, the estimated burden associated with reporting on this Objective was one minute, therefore by doubling the number of required measures from two to four, we are estimating the proposed time for CY 2022 would be 2 minutes (or an increase in 0.03 hours per reporting hospital). Although the Objective's Syndromic Surveillance Reporting measure is proposed to

change its setting for which data is required to be submitted, we don't anticipate the update from ''urgent care'' to ''emergency department'' to change burden hours given that the capacity to submit reports is already an existing part of built-in CEHRT functionality. Second is the proposed requirement for a new measure based on SAFER Guides Reporting, which we have anticipated will take one minute to report (as it is proposed to be completed via a single yes/no attestation response). The proposed inclusion of reporting on this SAFER Guides measure would increase the total burden by 0.02 hours. Lastly, we would like to note that the proposed inclusion of a new HIE Bi-Directional Exchange measure would not have any effect on the estimated reporting burden given that it would be offered as an optional, alternative reporting method to the two current Support Electronic Referral Loops measures, therefore resulting in no net change. Providers will only be required to respond with either the two existing measures OR choose the new Bi-Directional Exchange measure, but the amount of associated burden equals the same regardless of their selection and thus does not require any additional change in hours.

In proposing to continue the EHR reporting period as any self-selected 90-days in CY 2023 and any self-selected 180-days in CY 2024, we do not anticipate additional burden due to how the QualityNet attestation system is setup and operated to account for the estimated time spent with reporting (submitting automated reports via CEHRT or attesting to the Program's objectives and measures wouldn't be impacted by a longer EHR reporting period). A similar approach applies to the proposal for increasing the scoring threshold from 50 to 60 points, which does not require any expectation that submitting providers would endure a longer time duration of attesting to the Program, especially noting that all objectives and measures are currently required to be reported on (the threshold only indicates the minimum score necessary to be considered a meaningful EHR user). Finally, we do not believe that our proposals aligned with the Hospital IQR Program to add two eCQMs and remove four eCQMS from the eCQM measure set would affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program. Previously finalized policy requires hospitals to select eCQMs from the eCQM measure set on which to report (85 FR 58970 through 58976). In other words, while these proposals would result in new eCQMs being added to and some eCQMs being removed from the eCQM measure set, hospitals would not be required to report more than a total of four eCQMs as is currently required (85 FR 58970 through 58971). We believe these are appropriate burden estimates for reporting and have used this methodology in our collection of information burden estimates for this proposed rule.

Given the proposals, we estimate a total burden estimate of 6 hours 33 minutes per respondent (roughly 6.5 hours) which is an increase of 2 minutes from the FY 2021 IPPS/LTCH PPS final rule (85 FR 58432).

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden Per Respondent for CY 2022:
§ 495.24(e) - Objectives/Measures Medicare (Eligible Hospitals/CAHs)

Objective	Measure	Burden Estimate per Eligible Hospital and CAH
Protect Patient Health Information	Security Risk Analysis	6 hours
Protect Patient Health Information	SAFER Guides*	1 minute*
Electronic Prescribing	e-Prescribing	
	Query of PDMP	10 minutes
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	10 minutes
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	
	-OR-	
	Health Information Exchange Bi-Directional Exchange *	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	10 minutes
Public Health and Clinical Data Exchange	• Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry -Reporting • Electronic Reportable Laboratory Result Reporting	2 minutes*
Total Burden Estimate per Respondent		6 hours 33 minutes (6.5 hours)

*Indicates a proposed change to the estimated annual information collection burden per respondent.

(2) Hourly Labor Costs

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated a mean hourly rate of $63.46 for the staff involved in attesting to EHR technology, meaningful use objectives and associated measures, and electronically submitting the clinical quality measures. This reflected the mean hourly rate of a lawyer. We had previously used the mean hourly rate of $68.22 for the necessary staff involved in attesting to the objectives and measures under 42 CFR 495.24(e) in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42609). This rate was updated to $69.34 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59014) based upon then recently released 2018 data from the Bureau of Labor Statistics (BLS).[1525]

The Medicare Promoting Interoperability Program has previously utilized this lawyer hourly wage rate, however, we have determined that it is no longer the most accurate professional among the hospital staff members who are most likely to complete the program's required electronic responses and attestations for the Program. Rather, we believe hospital staff similar to the staff who report for the Hospital Inpatient Quality Reporting Program are utilized to report for the Medicare Promoting Interoperability Program, specifically, a medical records and health information technician staffing role. We believe that both current and anticipated labor performed by participating hospitals in order to successfully complete the Program's reporting requirements is accomplished by this technical role and not the position of a lawyer. Therefore, in properly calculating our estimated burden, we propose to replace the existing lawyer's wage rate of $69.34 with that of a medical records and health information technician's median wage rate ($20.50 according to the 2019 U.S. Bureau of Labor Statistics).[1526] If finalized, it would more accurately reflect the real-world scenario of those staff members performing the required labor.

We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with the Hospital IQR Program. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($20.50 × 2 = $41) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $41 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program.

In summary, if our proposals are finalized as proposed, we estimate a minimal increase in total burden hours for the Medicare Promoting Interoperability Program for CY 2022 (increase of 2 additional minutes per hospital). Using the median hourly wage for a medical records and health information technician, we estimate a burden cost increase for CY 2022 of $1.37 per hospital. We estimate the total annual burden of 21,450 burden hours across 3,300 responses for the Program's objectives and measures, and we estimate the total burden cost for CY 2022 to be $879,450 (21,450 hours × $41). Given that the total cost estimate for CY 2021 in last year's final rule was $1,487,343, these proposed updates would result in a net cost decrease of $607,893 for the Medicare Promoting Interoperability Program.

If our proposals are finalized as proposed for CY 2023 and CY 2024, we do not estimate any net change in total burden hours for the Medicare Promoting Interoperability Program when compared to CY 2022 estimates. CY 2023 proposals only include an extension of the current 90-day EHR reporting period and the adoption of two new eCQMs to the Program's eCQM measure set (in alignment with the proposals under the Hospital IQR Program), whereas CY 2024 proposals include a 180-day EHR reporting period and the removal of four eCQMs from the Program's eCQM measure set (in alignment with proposals under the Hospital IQR Program). Both proposals for CY 2023 and CY 2024 have already been detailed to create no net change to the total burden hours and therefore we estimate both years as having the same total cost of $879,450 (21,450 hours × $41).

The burden hours associated with reporting program requirements is currently approved under OMB control number 0938–1278. The updated burden cost estimates discussed in this section will be revised and submitted to OMB for final approval.

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden (Total Cost) Finalized for CY 2021

Regulations Section	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
42 CFR 495.24(e)	3,300	3,300	6.5	21,450	69.34	1,487,343

[1525] *https://www.bls.gov/oes/current/oes231011.htm.*

[1526] *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm#tab-1.* Accessed on [02/10/21].

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden (Total Cost) Proposed for CY 2022 – CY 2024

Regulations Section	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
42 CFR 495.24(e)	3,300	3,300	6.5	21,450	41.00	879,450

11. Summary of All Burden in This Proposed Rule

The following chart reflects the total burden and associated costs for the provisions included in this proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Inpatient Quality Reporting Program	+2,475	$101,475
Hospital Value-Based Purchasing Program	N/A	N/A
HAC Reduction Program	N/A	N/A
Hospital Readmissions Reduction Program[1]	N/A	N/A
Promoting Interoperability Programs [2]	N/A	-$607,893
LTCH Quality Reporting Program	+1	$159,516.72
PPS-Exempt Cancer Hospital Quality Reporting Program	-3	-$113
Market-Based MS-DRG Relative Weight Data Collection Requirement	-63,780	-$4,315,993
TOTAL	**-61,308**	**-4,822,54**

* Numbers rounded.

[1] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for-service claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[2] Medicare Promoting Interoperability Program indicates a reduced cost from the previous year due to how the designated role to report on program requirements has been updated to a Medical Records and Health Information Technician which utilizes a lower hourly wage rate.

C. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

I, Elizabeth Richter, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 16, 2021.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, and Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs-health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for Part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.1 is amended by revising paragraph (a)(1)(ii), adding paragraph (a)(7), and revising paragraph (b)(2) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) * * *

(ii) Payment for other costs related to inpatient hospital services is made on a reasonable cost basis as follows:

(A) Organ acquisition costs incurred by hospitals with approved organ transplant programs.

(B) The costs of qualified nonphysician anesthetist's services, as described in § 412.113(c).

(C) Direct costs of approved nursing and allied health educational programs.

(D) Costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant as described in § 412.113(e).

* * * * *

(7) This part implements section 1866(k) of the Act, which directs hospitals described in section 1886(d)(1)(B)(v) of the Act to submit data on quality measures to the Secretary.

(b) * * *

(2) Subpart B of this part sets forth all of the following:

(i)(A) The classifications of hospitals that are included in and excluded from the prospective payment systems specified in paragraph (a)(1) of this section.

(B) Requirements governing the inclusion or exclusion of hospitals in the systems as a result of changes in their classification.

(ii) Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

* * * * *

■ 3. Section 412.2 is amended by revising paragraph (e)(4) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(e) * * *

(4) The acquisition costs of hearts, kidneys, livers, lungs, pancreas, and intestines (or multivisceral organs) incurred by approved transplant programs.

* * * * *

■ 4. Section 412.23 is amended by adding paragraph (f)(3) to read as follows:

§ 412.23 Excluded Hospitals: Classifications.

* * * * *

(f) * * *

(3) *PCHQR Program.* All hospitals classified as cancer hospitals under this paragraph must comply with the requirements of the PPS-Exempt Cancer Hospital Quality Reporting Program, as described in § 412.24.

* * * * *

■ 5. Section 412.24 is added to read as follows:

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

(a) *Applicability.* The PCHQR Program applies to hospitals that are classified as cancer hospitals (PCHs) under the criteria described in § 412.23(f)(1) or (2).

(b) *Participation in the PCHQR Program.* In order to participate in the PCHQR Program, a PCH must do all of the following:

(1) Register with QualityNet (*http://qualitynet.cms.gov*) prior to reporting, including designating a QualityNet security official who completes all steps of the PCHQR Program registration process as described on the QualityNet website.

(2) Enroll in CDC's National Healthcare Safety Network (*https://www.cdc.gov/nhsn/enrollment/index.html*).

(c) *Submission of PCHQR Program data.* Except as provided in paragraph (e) of this section, PCHs that participate in the PCHQR Program must submit to CMS data on quality measures specified under section 1833(k)(3) of the Act in a form and manner, and at a time, specified by CMS. PCHs that participate in the PCHQR Program must also submit an annual online Data Accuracy and Completeness Acknowledgement via the QualityNet website (*http://qualitynet.cms.gov*) to attest to the accuracy and completeness of these data by the deadline specified by CMS on the QualityNet website (*http://qualitynet.cms.gov*).

(d) *Quality measure updates, retention, and removal*—(1) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the PCHQR Program. CMS announces technical measure specification updates through the QualityNet website (*http://qualitynet.cms.gov*) and listserv announcements.

(2) *Measure retention.* Except as provided in paragraph (d)(2)(ii) of this section, all quality measures specified under section 1866(k)(3) for the PCHQR Program measure set remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(3) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a quality measure based on one or more of the following factors:

(A) *Factor 1.* Measure performance among PCHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made.

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* The collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Exception.* CMS may retain a quality measure that meets one or more of the measure removal factors described in paragraph (d)(3)(i) of this section if the continued collection of data on the quality measure would align with a stated CMS or HHS policy objective, including, but not limited to, an objective to increase the number of quality measures that a PCH can report electronically, or an objective to collect data on the measure in one or more other CMS quality reporting programs.

(e) *Extraordinary circumstances exceptions (ECE).* (1) CMS may grant an ECE to a PCH that has requested an extension or exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the PCH.

(2) CMS may grant an ECE to one or more PCHs that has not requested an exception if CMS determines that—

(i) An extraordinary circumstance has affected an entire region or locale; or

(ii) A systemic problem with one of CMS's data collection systems has directly affected the ability of the PCH to submit data in accordance with paragraph (c) of this section.

(3) A PCH participating in the PCHQR Program that wishes to request an ECE must submit an ECE request to CMS via the QualityNet website (*https://qualitynet.cms.gov/pch/pchqr/resource*) within 90 days of the date that the extraordinary circumstances occurred, along with the following information:

(i) The PCH's CCN, name, reason for requesting an extension or exception, and evidence of the impact of extraordinary circumstances, including but not limited to photographs and media articles;

(ii) The date when the PCH will again be able to submit PCHQR Program data and a justification for that proposed date;

(iii) The following contact information for the PCH's CEO and any other designated personnel:

(A) Name.

(B) Email address.

(C) Telephone number.

(D) Physical mailing address (not a post office box); and

(iv) The signature of the PCH's CEO or designee on the ECE request.

(f) *Public reporting of PCHQR Program data.* CMS makes data submitted by PCHs under the PCHQR Program available to the public on the Provider Data Catalog website (*https://data.cms.gov/provider-data/*). Prior to making any such data submitted by a PCH available to the public, CMS gives the PCH an opportunity to review the data via the Hospital Quality Reporting (HQR) system (*https://hqr.cms.gov/hqrng/login*) and announces the timeline for review on the QualityNet

website (*http://qualitynet.cms.gov*) and applicable listservs.

■ 6. Section 412.64 is amended—

■ a. In paragraph (e)(1)(ii), by removing the phrase ''paragraph (e)(4) of this section'' and adding in its place the phrase ''paragraphs (e)(4) and (h)(4)(vii) of this section'';

■ b. In paragraph (e)(4) introductory text, by removing the phrase ''and the imputed floor under paragraph (h)(4)'' and adding in its place the phrase ''and, for discharges on or after October 1, 2004, and before October 1, 2018, the imputed floor under paragraph (h)(4)'';

■ c. In paragraph (h)(4) introductory text, by removing the phrase ''October 1, 2018, CMS establishes'' and adding in its place the phrase ''October 1, 2018, and for discharges on or after October 1, 2021, CMS establishes'';

■ d. In paragraph (h)(4)(vi) introductory text, by removing the phrase ''October 1, 2018, the minimum'' and adding in its place the phrase ''October 1, 2018, and for discharges on or after October 1, 2021, the minimum'';

■ e. By adding paragraph (h)(4)(vii); and

■ f. By revising paragraph (h)(5).

The addition and revision read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(h) * * *

(4) * * *

(vii) For discharges on or after October 1, 2021, the minimum wage index computed under this paragraph must not be applied in a budget neutral manner.

(5)(i) For purposes of paragraph (h)(4) of this section, for discharges on or after October 1, 2004 and before October 1, 2018, an all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural. For purposes of this definition, a State with rural areas and with hospitals reclassified as rural under § 412.103 is not an all-urban State.

(ii) For purposes of paragraph (h)(4) of this section, for discharges on or after October 1, 2021, an all-urban State is a State with no rural areas, as defined in this section, or a State in which there are no hospitals classified as rural under section 1886 of the Act. For purposes of this definition, a hospital is classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

* * * * *

■ 7. Section 412.71 is amended by revising paragraph (b)(3) to read as follows:

§ 412.71 Determination of base-year inpatient operating costs.

* * * * *

(b) * * *

(3) Kidney acquisition costs incurred by hospitals with approved kidney transplant programs as described in § 412.100. Kidney acquisition costs in the base year are determined by multiplying the hospital's average kidney acquisition cost per kidney times the number of kidney transplants covered by Medicare Part A during the base period.

* * * * *

■ 8. Section 412.90 is amended by revising paragraph (d) to read as follows:

§ 412.90 General rules.

* * * * *

(d) *Kidney acquisition costs incurred by hospitals with approved kidney transplant programs.* CMS pays for kidney acquisition costs incurred by kidney transplant programs on a reasonable cost basis. The criteria for this special payment provision are set forth in § 412.100.

* * * * *

■ 9. Section 412.96 is amended by revising paragraphs (c)(1) introductory text, (h)(1), and (i)(1) and (2) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(c) * * *

(1) *Case-mix index.* CMS sets forth national and regional case-mix index values in each year's annual notice of prospective payment rates published under § 412.8(b). The methodology CMS uses to calculate these criteria is described in paragraph (h) of this section. The case-mix index value to be used for an individual hospital in the determination of whether it meets the case-mix index criteria is that calculated by CMS from the hospital's own billing records for Medicare discharges as processed by the fiscal intermediary and submitted to CMS. The hospital's case-mix index for discharges (not including discharges from units excluded from the prospective payment system under subpart B of this part) during the same Federal fiscal year used to compute the case mix index values under paragraph (h) of this section must be at least equal to—

* * * * *

(h) * * *

(1) *Updating process.* CMS updates the national and regional case-mix index standards using the best available data from hospitals subject to the prospective payment system for the Federal fiscal year.

* * * * *

(i) * * *

(1) *Updating process.* CMS updates the national and regional number of discharges using the best available data for levels of admissions or discharges or both.

(2) *Source of data.* In making the calculations described in paragraph (i)(1) of this section, CMS uses the best available hospital admissions or discharge data.

* * * * *

■ 10. Section 412.100 is revised to read as follows:

§ 412.100 Special treatment: Kidney transplant programs.

(a) *Adjustments for kidney transplant programs.* (1) CMS adjusts the inpatient prospective payment system (IPPS) rates for inpatient operating costs determined under subparts D and E of this part for hospitals with approved kidney transplant programs (discussed at § 482.104) to remove the net costs associated with kidney acquisition.

(2)(i) Payment for Medicare kidney acquisition costs, as set forth in subpart L of part 413 of this chapter, is made on a reasonable cost basis apart from the prospective payment rate for inpatient operating costs.

(ii) IPPS payment to the hospital is adjusted in each cost reporting period to reflect an amount necessary to compensate the hospital for reasonable costs of Medicare kidney acquisition.

(b) *Costs of kidney acquisition.* Kidney acquisition costs include costs incurred in the acquisition of a kidney from a living or a cadaveric donor, by the hospital or an organ procurement organization, as appropriate. These costs are listed in § 413.402(b) of this chapter.

■ 11. Section 412.103 is amended by—

■ a. Revising paragraph (g)(3);

■ b. Redesignating paragraph (g)(4) as (g)(5); and

■ c. Adding a new paragraph (g)(4).

The revision and addition read as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

* * * * *

(g) * * *

(3) *Cancellation of rural reclassification on or after October 1, 2019, and before October 1, 2021.* For all written requests submitted by hospitals on or after October, 1, 2019, and before October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS

Regional Office not less than 120 days prior to the end of a Federal fiscal year. The hospital's cancellation of the classification is effective beginning with the next Federal fiscal year.

(4) *Cancellation of rural reclassification on or after October 1, 2021.* For all written requests submitted by hospitals on or after October 1, 2021, to cancel rural reclassifications, a hospital may cancel its rural reclassification by submitting a written request to the CMS Regional Office not less than 1 calendar year after the effective date of the rural reclassification. The hospital's cancellation of the classification is effective beginning the Federal fiscal year that begins in the calendar year following the calendar year in which the cancelation request is submitted.

* * * * *

■ 12. Section 412.105 is amended by adding paragraph (f)(1)(iv)(C)(*3*) and revising paragraphs (f)(1)(v)(F), (f)(1)(vii), and (f)(1)(x) to read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(C) * * *

(*3*) Effective for portions of cost reporting periods beginning on or after July 1, 2023, a hospital may qualify to receive an increase in its otherwise applicable FTE resident cap if the criteria specified in § 413.79(p) of this subchapter are met.

* * * * *

(v) * * *

(F)(*1*) Subject to the provisions of paragraph (f)(1)(x) of this section, effective for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2022, full-time equivalent residents at an urban hospital in a rural track program are included in the urban hospital's rolling average calculation described in paragraph (f)(1)(v)(B) of this section.

(*2*) Subject to the provisions of paragraph (f)(1)(x) of this section, for cost reporting periods beginning on or after October 1, 2022, for each rural track started, full-time equivalent residents at an urban hospital or rural hospital in a rural track program are excluded from the rolling average calculation described in paragraph (f)(1)(v)(B) of this section during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

* * * * *

(vii)(A) If a hospital establishes a new medical residency training program, as defined in § 413.79(l) of this subchapter, the hospital's full-time equivalent cap may be adjusted in accordance with the provisions of § 413.79(e) of this subchapter.

(B)(*1*) A hospital that, as of December 27, 2020, has a full-time equivalent cap of less than 1.0 FTE based on a cost reporting period beginning before October 1, 1997, that begins training residents in a new medical residency training program, as defined at § 413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020, and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains at least 1.0 FTE in such new medical residency training program(s), to be calculated in accordance with § 413.79(e) of this subchapter.

(*2*) A hospital that has a full-time equivalent cap of no more than 3.0 FTEs based on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, that begins training residents in a new medical residency training program, as defined at § 413.79(l) of this subchapter, in a cost reporting period beginning on or after December 27, 2020 and before December 26, 2025, may receive an adjustment to its full-time equivalent cap when it trains more than 3.0 FTE in such new medical residency training program(s), to be calculated in accordance with the provisions of § 413.79(e) of this subchapter.

* * * * *

(x)(A) For rural track programs started in a cost reporting period beginning before October 1, 2022, an urban hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter), or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks in accordance with the applicable provisions of § 413.79(k) of this subchapter.

(B) For cost reporting periods beginning on or after October 1, 2022, an urban hospital or rural hospital that establishes a new residency program (as defined in § 413.79(l) of this subchapter) with a rural track, or adds an additional rural track, may include in its FTE count residents in those rural tracks in accordance with the applicable provisions of § 413.79(k) of this subchapter.

* * * * *

■ 13. Section 412.106 is amended by—

■ a. Revising paragraph (b)(4)(i)

■ b. Removing paragraph (b(4)(ii) and redesignating paragraphs (b(4)(iii) and (iv) as (b(4)(ii) and (iii), respectively;

■ c. Revising paragraph (g)(1)(iii)(C)(*8*); and

■ d. Adding paragraph (g)(1)(iii)(C)(*9*).

The revisions and addition read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) * * *

(4) * * *

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan that includes coverage for inpatient hospital care on that day or directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*8*) For each subsequent fiscal year, for all eligible hospitals, except Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the most recent cost reporting year for which audits have been conducted.

(*9*) For fiscal year 2022, for Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, CMS will base its estimates of the amount of hospital uncompensated care on utilization data for Medicaid and Medicare Supplemental Security Income (SSI) patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals,

a proxy for Medicare SSI utilization data).

* * * * *

■ 14. Section 412.113 is amended by revising paragraph (d) to read as follows:

§ 412.113 Other payments.

* * * * *

(d) *Organ acquisition.* Payment for organ acquisition costs as specified in part 413, subpart L, incurred by hospitals with approved transplant programs is made on a reasonable cost basis.

* * * * *

■ 15. Section 412.116 is amended by revising paragraph (c) to read as follows:

§ 412.116 Method of payment.

* * * * *

(c) *Special interim payments for certain costs.* For capital-related costs for cost-reporting periods beginning before October 1, 1991, and the direct costs of medical education, which are not included in prospective payments but are reimbursed as specified in §§ 413.130 and 413.85 of this chapter, respectively, interim payments are made subject to final cost settlement. Interim payments for capital-related items for cost-reporting periods beginning before October 1, 1991, and the estimated cost of approved medical education programs (applicable to inpatient costs payable under Medicare Part A and for kidney acquisition costs in hospitals with approved kidney transplant programs) are determined by estimating the reimbursable amount for the year based on the previous year's experience and on substantiated information for the current year and divided into 26 equal biweekly payments. Each payment is made 2 weeks after the end of a biweekly period of services, as described in § 413.64(h)(5) of this subchapter. The interim payments are reviewed by the intermediary at least twice during the reporting period and adjusted if necessary.

* * * * *

§ 412.140 [Amended]

■ 16. Section 412.140 is amended—

■ a. In paragraph (a)(1), by removing the term ''QualityNet.org'' and adding in its place the terms ''QualityNet website'';

■ b. In paragraph (a)(2), by removing the term ''QualityNet Administrator'' and adding in its place the phrase ''QualityNet security official'';

■ c. In paragraph (c)(2)(i), by removing the term ''QualityNet.org'' and adding in its place the terms ''QualityNet website''; and

■ d. In paragraph (e)(2)(iii), by removing the term ''QualityNet system administrator'' and adding in its place the phrase ''QualityNet security official''.

■ 17. Section 412.154 is amended by revising paragraph (f)(4) to read as follows:

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(f) * * *

(4) CMS posts the excess readmission ratios for the applicable conditions for a fiscal year for each applicable hospital on the Hospital Compare website or successor website(s).

§ 412.160 [Amended]

■ 18. Section 412.160 is amended in the introductory text by removing the phrase ''in §§ 412.161 through 412.167'' and adding in its place the phrase ''in §§ 412.161 through 412.168''.

§ 412.163 [Amended]

■ 19. Section 412.163 is amended in paragraph (d) by removing the phrase ''the *Hospital Compare* Website'' and adding in its place the phrase ''the *Hospital Compare* website, which can be accessed via the Care Compare website at *https://www.medicare.gov/care-compare/*''.

§ 412.164 [Amended]

■ 20. Section 412.164 is amended- in paragraph (b) by removing the phrase ''the *Hospital Compare* Website'' and adding in its place the phrase ''the *Hospital Compare* website, which can be accessed via the Care Compare website at *https://www.medicare.gov/care-compare/*''.

§ 412.165 [Amended]

■ 21. Section 412.165 is amended—

■ a. In paragraph (c)(2), by removing ''QualityNet website (*QualityNet.org*)'' and adding in its place ''QualityNet website (*https://www.qualitynet.cms.gov*)''; and

■ b. In paragraph (c)(4), by removing ''QualityNet website (see *https://www.qualitynet.org*)'' and adding in its place ''QualityNet website (*https://www.qualitynet.cms.gov*)''.

§ 412.167 [Amended]

■ 22. Section 412.167 is amended in paragraph (b)(5) by removing ''QualityNet System Administrator'' and adding in its place ''QualityNet security official''.

■ 23. Section 412.168 is added to read as follows:

§ 412.168 Special rule for FY 2022.

(a) This section sets forth the scoring and payment methodology for the fiscal year 2022 Hospital VBP Program.

(b) CMS will calculate a measure rate for all measures selected under § 412.164(a) for fiscal year 2022 but will only apply § 412.165(a) to the measures included in the Clinical Outcomes Domain for that fiscal year, which are the following:

(1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI)

(2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF)

(3) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN (updated cohort))

(4) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30–COPD)

(5) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG)

(6) Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE)

(c) CMS will calculate a domain score for the measures described in paragraph (b)(1) of this section for hospitals that report the minimum number of measures in the Clinical Outcomes Domain.

(d) CMS will not award a Total Performance Score to any hospital.

(e) The total amount available for value-based incentive payments for fiscal year 2022 is equal to the total amount of base-operating DRG payment reductions for that fiscal year, as estimated by the Secretary.

(f) CMS will award value-based incentive payment percentages (as defined in § 412.160) for all hospitals to ensure that each hospital receives an incentive payment amount equal to the amount of the reduction made to its base-operating DRG payment amounts.

■ 24. Section 412.172 is amended by revising paragraph (f)(4) to read as follows:

§ 412.172 Reporting of hospital specific information.

* * * * *

(f) * * *

(4) CMS posts the total hospital-acquired condition score, the domain score, and the score on each measure for each hospital on the Hospital Compare website or successor website.

* * * * *

■ 25. Section 412.278 is amended by revising the first sentence of paragraph (b)(1) and revising paragraph (f)(2)(ii) to read as follows:

§ 412.278 Administrator's review.

* * * * *

(b) * * *

(1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor, in the manner directed by the Office of the Attorney Advisor. * * *

* * * * *

(f) * * *

(2) * * *

(ii) Not later than 105 days following issuance of the MGCRB decision in the case of review at the discretion of the Administrator, except the Administrator may, at his or her discretion, for good cause shown, toll such 105 days.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 26. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 27. Section 413.1 is amended by revising the paragraphs (a)(2)(v) and (d)(2)(i) to read as follows:

§ 413.1 Introduction.

(a) * * *

(2) * * *

(v) Organ procurement organizations (OPOs) and histocompatibility laboratories.

* * * * *

(d) * * *

(2) * * *

(i) Payment for the following is described in § 412.113 of this chapter:

(A) Capital related costs for cost reporting periods beginning before October 1991.

(B) Medical education costs.

(C) Organ acquisition costs as specified in part 413, subpart L.

(D) The costs of certain anesthesia services.

* * * * *

■ 28. Section 413.20 is amended by revising paragraph (d)(3) to read as follows:

§ 413.20 Financial data and reports.

* * * * *

(d) * * *

(3)(i) The provider must furnish the contractor, upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

* * * * *

■ 29. Section 413.24 is amended by revising paragraphs (f)(5)(i) introductory text and (f)(5)(i)(A) to read as follows:

§ 413.24 Adequate cost data and cost finding.

* * * * *

(f) * * *

(5) * * *

(i) The provider must accurately complete and submit the required cost reporting forms, including all necessary signatures and supporting documents. For providers claiming costs on their cost reports that are allocated from a home office or chain organization, the Home Office Cost statement must be submitted by the home office or chain organization as set forth in paragraph (f)(5)(i)(E) of this section. A cost report is rejected for lack of supporting documentation if it does not include the following, except as provided in paragraph (f)(5)(i)(E) of this section:

(A) *Teaching hospitals.* For teaching hospitals, effective for cost reporting periods beginning on or after October 1, 2021, the Intern and Resident Information System (IRIS) data which must contain the same total counts of direct GME FTE residents (unweighted and weighted) and IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the provider's cost report.

* * * * *

■ 30. Section 413.40 is amended by revising paragraph (a)(3) to read as follows:

§ 413.40 Ceiling on the rate of increase in hospital inpatient costs.

(a) * * *

(3) *Net inpatient operating costs* include the costs of certain preadmission services as specified in paragraph (c)(2) of this section, the costs of routine services, ancillary services, and intensive care services (as defined in § 413.53(b)) incurred by a hospital in furnishing covered inpatient services to Medicare beneficiaries. Net inpatient operating costs exclude capital-related costs as described in § 413.130, the costs of approved medical education programs as described in §§ 413.75 through 413.83 and 413.85, and organ acquisition costs as specified in subpart L of this part incurred by approved transplant programs. These costs are identified and excluded from inpatient operating costs before the application of the ceiling.

* * * * *

§ 413.75 [Amended]

■ 31. Section 413.75 is amended in paragraph (b), in the definition of ''Rural track FTE limitation'', by removing the phrase ''urban hospital may include in its'' and adding in its place the phrase ''urban hospital or rural hospital may include in its''.

■ 32. Section 413.77 is amended by revising paragraph (e)(1)(iii) and adding paragraphs (e)(1)(iv) and (v) to read as follows:

§ 413.77 Direct GME payments: Determination of per resident amounts.

* * * * *

(e) * * *

(1) * * *

(iii) If, under paragraph (e)(1)(ii)(A) or paragraph (B) or (e)(iv)(B) of this section, there are fewer than three existing teaching hospitals with per resident amounts that can be used to calculate the weighted mean value per resident amount, for base periods beginning on or after October 1, 1997, the per resident amount equals the updated weighted mean value of per resident amounts of all hospitals located in the same census region as that term is used in subpart D of part 412 of this subchapter.

(iv) A hospital that, as of December 27, 2020, has a per resident amount based on less than 1.0 FTE in any cost reporting period beginning before October 1, 1997, would receive a recalculated per resident amount when it trains at least 1.0 FTE in such program(s) for any cost reporting period beginning between December 27, 2020, and December 26, 2025. A hospital that, as of December 27, 2020, has a per resident amount based on no more than 3.0 FTEs in any cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, would receive a recalculated per resident amount when it trains more than 3.0 FTEs in such program(s) for any cost reporting period beginning between December 27, 2020 and December 26, 2025. The recalculated per resident amount is based on the lower of—

(A) The hospital's actual cost per resident incurred in connection with the GME program(s) based on the cost and resident data from the hospital's base year cost reporting period, which is, for hospitals with previously less than 1.0

FTE, the cost reporting period beginning on or after December 27, 2020, and before December 25, 2025, in which it trains at least 1.0 FTE; and for hospitals with previously less than or equal to 3.0 FTEs, the cost reporting period beginning on or after December 27, 2020, and before December 27, 2025, in which it trains more than 3.0 FTEs; or

(B) The updated weighted mean value of per resident amounts of all hospitals located in the same geographic wage area is calculated using all per resident amounts (including primary care and obstetrics and gynecology and nonprimary care) and FTE resident counts from the most recently settled cost reports of those teaching hospitals.

(v) Effective for a cost reporting periods beginning on or after December 27, 2020, a per resident amount would be established if a hospital trains less than 1.0 FTE resident and this training results from the hospital's participation in a Medicare GME affiliation agreement under § 413.79(f). Effective for a cost reporting period beginning on or after December 27, 2020, a per resident amount would only be established when the hospital trains at least 1.0 FTE and does not participate in a Medicare GME affiliation agreement under § 413.79(f) for that training.

* * * * *

■ 32. Section 413.78 is amended by revising paragraph (b) to read as follows:

§ 413.78 Direct GME payments: Determination of the total number of FTE residents.

* * * * *

(b)(1) No individual resident may be counted as more than one FTE based on the total time spent in training at all sites. A hospital cannot claim the time spent by residents training at another hospital, except as provided in paragraph (i) of this section. Except as provided in paragraphs (c), (d), and (e) of this section, if a resident spends time in more than one hospital or in a non-provider setting, the resident counts as partial FTE based on the proportion of time worked at the hospital to the total time worked. A part-time resident counts as a partial FTE based on the proportion of allowable time worked compared to the total time necessary to fill a full-time internship or residency slot.

(2) Effective for a cost reporting period beginning on or after December 27, 2020, a hospital must report FTE residents on its Medicare cost report for a cost reporting period if it does not participate in a Medicare GME affiliation agreement (as defined under § 413.75(b), and the hospital trains at least 1.0 FTE in an approved program or programs, or, if the hospital trains less than 1.0 FTE residents in an approved program or programs and this training results from the hospital's participation in a Medicare GME affiliation agreement (as defined under § 413.75(b)).

* * * * *

■ 34. Section 413.79 is amended by—

■ a. Revising paragraph (c)(2) introductory text;

■ b. Adding paragraph (c)(7);

■ c. Revising paragraph (d)(7);

■ d. Adding paragraphs (e)(1)(vi), (e)(6), and (f)(8);

■ e. Revising paragraphs (k) introductory text, (k)(1), (k)(2) introductory text, (k)(2)(i), and (k)(3);

■ f. Adding paragraph (k)(4)(i)(C);

■ g. Revising paragraph (k)(4)(ii) introductory text;

■ h. Adding (k)(4)(ii)(C);

■ i. In paragraph (k)(5)(i), removing the phrase ''An urban hospital may not include in its rural track FTE limitation or (assuming the urban hospital's FTE'' and adding in its place the phrase ''A hospital may not include in its rural track FTE limitation or (assuming the hospital's FTE'';

■ j. In paragraph (k)(5)(ii), removing the phrase ''The hospital'' and adding in its place the phrase ''Each hospital''; and

■ k. Adding paragraphs (k)(5)(iv) and (p).

The revisions and additions read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(c) * * *

(2) *Determination of the FTE resident cap.* Subject to the provisions of paragraphs (c)(3) through (6) and (m) through (p) of this section and § 413.81, for purposes of determining direct GME payment—

* * * * *

(7) *Determination of an increase in the otherwise applicable resident cap under section 126 of Public Law 116–260.* For portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

(d) * * *

(7)(i) Subject to the provisions under paragraph (k) of this section, effective for cost reporting periods beginning on or after April 1, 2000 and before cost reporting periods beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital are included in the urban hospital's rolling average calculation described in this paragraph (d).

(ii) Subject to the provisions under paragraph (k) of this section, effective for rural track programs started in a cost reporting period beginning on or after October 1, 2022, FTE residents in a rural track program at an urban hospital or rural hospital are excluded from rolling average calculation described in this paragraph (d) during the cost reporting periods prior to the beginning of the applicable hospital's cost reporting period that coincides with or follows the start of the sixth program year of each rural track.

(e) * * *

(1) * * *

(vi) In the case of a hospital that, as of December 27, 2020, has a FTE cap based on the training of less than 1.0 FTE in any cost reporting period beginning before October 1, 1997; or no more than 3.0 FTEs based on a cost reporting period beginning on or after October 1, 1997, and before December 27, 2020, if such a hospital begins training residents in a new approved program (as defined under § 413.79(l)) in a program year beginning on or after December 27, 2020 and before December 26, 2025, such hospital with a previous FTE cap of less than 1.0 FTE may receive a recalculated FTE cap when it begins to train at least 1.0 FTE in such new program(s); and such hospital with a previous FTE cap of no more than 3.0 FTEs may receive a recalculated FTE cap when it begins to train more than 3.0 FTEs in such new program(s). The recalculated FTE cap is equal to the sum of the products of three factors (limited to the number of accredited slots for each program):

(A) The highest total number of FTE residents trained in any program year during the fifth year of the first new program's existence started in a program year beginning on or after December 27, 2020 and before December 26, 2025, at all of the hospitals to which the residents in the program rotate;

(B) The number of years in which residents are expected to complete the program, based on the minimum accredited length for each type of program.

(C) The ratio of the number of FTE residents in the new program that trained at the hospital over the entire 5-year period to the total number of FTE residents that trained at all hospitals over the entire 5-year period.

* * * * *

(6) Effective for a cost reporting period beginning on or after December

27, 2020, FTE resident caps are established when the hospital trains 1.0 or more FTE residents in a new medical residency program (as defined under § 413.79(l) of this subchapter).

(f) * * *

(8) FTE resident cap slots added under section 126 of Pub. L. 116–260 may be used in a Medicare GME affiliation agreement beginning in the fifth year after the effective date of those FTE resident cap slots.

* * * * *

(k) *Residents training in rural track programs.* Subject to the provisions of § 413.81, an urban hospital that establishes a new residency program, or has an existing residency program, with a rural track (or an integrated rural track) may include in its FTE count residents in those rural tracks, in addition to the residents subject to its FTE cap specified under paragraph (c) of this section. An urban hospital (or, effective for a cost reporting period beginning on or after October 1, 2022, a rural hospital) with a rural track residency program may count residents in those rural tracks up to a rural track FTE limitation if the hospital complies with the conditions specified in paragraphs (k)(2) through (7) of this section.

(1) If an urban hospital rotates residents to a separately accredited rural track program at a rural hospital(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and before October 1, 2022, the urban hospital may include those residents in its FTE count for the time the rural track residents spend at the urban hospital, not to exceed its rural track FTE limitation. For cost reporting periods beginning on or after October 1, 2022, if an urban hospital rotates residents to a rural track program at a rural hospital(s) for more than one-half of the duration of the program, both the urban and the rural hospital may include those residents in their FTE counts for the time the rural track residents spend at the urban and rural hospital, respectively, not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average at paragraph (d)(7) of this section, training in the rural track at the urban hospital. For rural track programs started in a cost reporting period on or after October 1, 2022, before the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the rural track at the urban or rural hospital.

(ii) For rural track programs started prior to October 1, 2012, beginning with the fourth year of the rural track's existence, the rural track FTE limitation is equal to the product of the highest number of residents, in any program year, who during the third year of the rural track's existence are training in the rural track at the urban hospital and are designated at the beginning of their training to be rotated to the rural hospital(s) for at least two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, and the number of years those residents are training at the urban hospital. For rural track programs started on or after October 1, 2012 and before October 1, 2022, beginning with the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section. For rural track programs started on or after October 1, 2022, beginning with the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation is calculated in accordance with paragraph (e)(1) of this section.

(2) If an urban hospital rotates residents to a separately accredited rural track program at a rural nonprovider site(s) for two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for more than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(d) through (g). For cost reporting periods beginning on or after October 1, 2022, if an urban or rural hospital rotates residents to a rural track program at a rural nonprovider site for more than one-half of the duration of the program, the urban or rural hospital may include those residents in its FTE count, subject to which hospital meets the requirements under § 413.78(g), not to exceed their rural track FTE limitations. The rural track FTE limitation is determined as follows:

(i) For rural track programs started prior to October 1, 2012, for the first 3 years of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For rural track programs started on or after October 1, 2012, and before October 1, 2022, prior to the start of the urban hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each urban hospital will be the actual number of FTE residents, subject to the rolling average specified in paragraph (d)(7) of this section, training in the rural track at the urban hospital and the rural nonprovider site(s). For rural track programs started in a cost reporting period on or after October 1, 2022, prior to the start of the urban or rural hospital's cost reporting period that coincides with or follows the start of the sixth program year of the rural track's existence, the rural track FTE limitation for each hospital will be the actual number of FTE residents training in the rural track at the hospital and the rural nonprovider site(s).

* * * * *

(3) For rural track programs started prior to October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for less than two-thirds of the duration of the program for cost reporting periods beginning on or after April 1, 2000, and before October 1, 2003, or for one-half or less than one-half of the duration of the program for cost reporting periods beginning on or after October 1, 2003, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under

paragraph (e)(3) of this section, or the rural *hospital's FTE* count does not exceed that *hospital's FTE* cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started on or after October 1, 2012, if an urban hospital rotates residents in the rural track program to a rural hospital(s) for one-half or less than one-half of the duration of the program, the rural hospital may not include those residents in its FTE count (unless the rural track is a new program under *paragraph (e)(3)* of this section, or the rural *hospital's FTE* count does not exceed that *hospital's FTE* cap), nor may the urban hospital include those residents when calculating its rural track FTE limitation. For rural track programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(4) * * *

(i) * * *

(C) For rural track programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(ii) For rural track programs started on or after October 1, 2012 and prior to October 1, 2022, if an urban hospital rotates residents in the rural track program to a rural nonprovider site(s) for one-half or less than one-half of the duration of the program, the urban hospital may include those residents in its FTE count, subject to the requirements under § 413.78(g). The urban hospital may include in its FTE count those residents in the rural track, not to exceed its rural track limitation, determined as follows:

* * * * *

(C) For rural track programs started in a cost reporting period beginning on or after October 1, 2022, if less than or equal to 50 percent of the duration of the training program occurs in a rural area, neither the urban or rural hospital may receive a rural track FTE limitation.

(5) * * *

(iv) Effective for cost reporting periods beginning on or after October 1, 2022, in order for an urban or rural hospital to receive a rural track FTE limitation, greater than 50 percent of the rural track program must occur in a rural area.

* * * * *

(p) *Determination of an increase in the otherwise applicable resident cap under section 126 of the Consolidated Appropriations Act (Pub. L. 116–260).* For portions of cost reporting periods beginning on or after July 1, 2023, a hospital may receive an increase in its otherwise applicable FTE resident cap (as determined by CMS) if the hospital meets the requirements and qualifying criteria under section 1886(h)(9) of the Act and if the hospital submits an application to CMS within the timeframe specified by CMS.

Subpart H—Payment for End-Stage Renal Disease (ESRD) Services

■ 35. The subpart heading for Subpart H is revised to read as set forth above.

§ § 413.200 through 413.203 [Removed and Reserved]

■ 36. Sections 413.200 through 413.203 are removed and reserved.

■ 37. Subpart L is added to read as follows:

Subpart L—Payment of Organ Acquisition Costs to Transplant Hospitals and Organ Procurement Organizations

Sec.

Subpart L—Payment of Organ Acquisition Costs to Transplant Hospitals and Organ Procurement Organizations

§ 413.400 Definitions.

As used in this subpart:

Histocompatibility laboratory means a laboratory meeting the requirements set forth in § 493.1227 of this chapter and providing the services for the acquisition of kidneys or other organs for transplantation.

Hospital-based organ procurement organization (HOPO) means an organ procurement organization that is considered a department of the transplant hospital and reports organ acquisition costs it incurs on the transplant hospital's Medicare cost report.

Independent organ procurement organization (IOPO) means an organ procurement organization that files a Medicare cost report separate from a hospital and meets all of the following:

(1) Is not subject to the control of a hospital with respect to the hiring, firing, training, and paying of employees.

(2) Is not considered as a department of a hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

(3) Reports organ acquisition costs it incurs on the IOPO Medicare cost report.

Organ, for organ acquisition payment purposes, means:

(1) A human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

(2) Pancreata procured on or after October 1, 2004 for the purpose of acquiring pancreatic islet cells for transplantation into individuals who are participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

Organ procurement organization (OPO) means an organization defined in § 486.302 of this chapter. OPOs can be independent or hospital based.

Standard acquisition charge (SAC) means a charge as defined in § 413.404 of this chapter.

Transplant hospital means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Transplant hospital/HOPO (TH/HOPO) refers to a transplant hospital, or a transplant hospital that operates a HOPO (as previously defined in this section) and performs organ procurement activities as one entity reported on the transplant hospital's Medicare cost report.

Transplant program means an organ-specific transplant program within a transplant hospital (as defined in this section).

§ 413.402 Organ acquisition costs.

(a) *Costs related to organ acquisition.* Costs recognized in paragraph (b) of this section are costs incurred in the acquisition of organs from a living donor or a cadaveric donor, by the hospital or an organ procurement organization, as appropriate.

(b) *Types of costs.* Organ acquisition costs are as follows:

(1) Tissue typing, including tissue typing furnished by independent laboratories.

(2) Donor and beneficiary evaluation.

(3) Other costs associated with excising organs, such as general routine and special care services provided to the donor.

(4) Operating room and other inpatient ancillary services applicable to the donor.

(5) Preservation and perfusion costs.

(6) Organ Procurement and Transplantation Network registration fees.

(7) Surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys).

(8) Transportation of the excised organ to the transplant hospital.

(9) Costs of organs acquired from other hospitals or organ procurement organizations.

(10) Hospital costs normally classified as outpatient costs applicable to organ excisions (services include donor and recipient tissue typing, work-up, and related services furnished prior to inpatient admission).

(11) Costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs.

(12) All pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, surgeons' fees for cadaveric excisions, and the costs of physicians' services.

(c) *Living kidney donor complications.* (1) Living kidney donor complications related to the surgery to remove a kidney, which occur after the date of discharge, are not considered kidney acquisition costs.

(2) Medicare covers costs incurred for living kidney donor complications only if they are directly attributable to a kidney donation for transplant into a Medicare beneficiary.

(3) Living kidney donor complications are paid under Medicare Part A or Part B, as applicable to the services provided, with no donor liability for deductibles or coinsurance. Living kidney donor complications are billed under the Medicare Beneficiary Identifier of the transplant recipient.

§ 413.404 Standard acquisition charge.

(a) *General.* (1) Procuring an organ is not a covered service when performed independent of a Medicare covered transplant, however, the reasonable costs to procure an organ are reimbursable when billed in connection with a Medicare covered transplant.

(2) The SAC represents the average of the total actual costs associated with procuring either cadaveric donor organs or living donor organs, by organ type.

(3) When a TH/HOPO or IOPO provides an organ to another transplant hospital or OPO, it bills its SAC to the transplant hospital, TH/HOPO or IOPO receiving the organ.

(b) *THs/HOPOs SACs.* (1) A TH/HOPO must develop a SAC for each organ type (for example heart, liver, or lung).

(2) When a TH/HOPO provides an organ to another transplant hospital or OPO, it must bill the receiving transplant hospital or OPO its SAC by organ type, or the hospital's standard departmental charges that are reduced to cost.

(3) A transplant hospital must establish SACs for living donor organs. A TH/HOPO must establish SACs for cadaveric donor organs.

(i) *Living donor SAC for transplant hospitals*—(A) *Definition.* The living donor SAC is an average cost that a transplant hospital incurs to procure an organ from a living donor.

(B) *Establishment of living donor SAC.* A transplant hospital must establish a living donor SAC (living SAC) before the transplant hospital bills its first living donor transplant to Medicare.

(C) *Calculating the living donor SAC*—(*1*) *Initial living donor SAC.* A transplant hospital calculates its initial living SAC for each living organ type as follows:

(*i*) By estimating the reasonable and necessary costs they expect to incur for services furnished to living donors, and pre-admission services furnished to recipients of living donor organs during the hospital's cost reporting period.

(*ii*) Dividing the estimated amount described in paragraph (b)(3)(i)(C)(*1*)(*i*) of this paragraph by the projected number of usable living donor organs to be procured by the transplant hospital during the transplant hospital's cost reporting period.

(*2*) *Subsequent living donor SAC.* A transplant hospital calculates its subsequent living donor SAC for each living organ type as follows:

(*i*) By using the transplant hospital's actual organ acquisition costs for the living donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) Dividing the costs in paragraph (b)(3)(i)(C)(*2*)(*i*) of this section by the actual number of usable living organs procured by the transplant hospital during that prior cost reporting period.

(D) *Costs used to develop the living donor SAC.* Costs that may be used to develop the living donor SAC include, but are not limited to the following:

(*1*) Costs of tissue typing services, including those furnished by independent laboratories.

(*2*) Costs of physician pre-admission transplant evaluation services.

(*3*) Organ Procurement and Transplantation Network registration fees.

(*4*) Costs for donor and recipient evaluation and workup furnished prior to admission for transplantation.

(*5*) Other costs associated with procurement, for example, general routine and special care services related to the donor.

(*6*) Costs of operating room and other inpatient ancillary services related to the donor.

(*7*) Preservation and perfusion costs.

(*8*) Transportation costs of the excised organ.

(ii) *Cadaveric donor SAC for THs/HOPOs*—(A) *Definition.* The cadaveric donor SAC is an average cost that a TH/HOPO incurs to procure a cadaveric donor organ.

(B) *Calculating the cadaveric SAC*—(*1*) *Initial cadaveric donor SAC.* A TH/HOPO calculates its initial cadaveric SAC for each cadaveric organ type as follows:

(*i*) By estimating the reasonable and necessary costs they expect to incur to procure cadaveric organs, combined with the expected costs of acquiring cadaveric organs from OPOs or other transplant hospitals.

(*ii*) Dividing the estimated amount described in paragraph (b)(3)(ii)(B)(*1*)(*i*) of this section by the projected number of usable cadaveric organs to be procured by the TH/HOPO within the transplant hospital's cost reporting period.

(*2*) *Subsequent cadaveric donor SAC.* A TH/HOPO calculates its subsequent cadaveric donor SAC for each cadaveric organ type as follows:

(*i*) By using the transplant hospital's actual organ acquisition costs for the cadaveric donor organ type from the prior year's Medicare cost report, adjusted for any changes in the current year.

(*ii*) Dividing the costs in paragraph (b)(3)(ii)(B)(*2*)(*i*) of this section by the actual number of usable cadaveric organs procured by the TH/HOPO during that prior cost reporting period.

(C) *Costs to develop the cadaveric donor SAC.* Costs that may be used to develop the cadaveric donor SAC include, but are not limited to the following:

(*1*) Costs of organs acquired from other transplant hospitals or OPOs.

(*2*) Costs of transportation of the excised organs.

(*3*) Surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys).

(*4*) Costs of tissue typing services, including those furnished by independent laboratories.

(*5*) Preservation and perfusion costs.

(*6*) General routine and special care service costs.

(*7*) Operating room and other inpatient ancillary service costs.

(c) *Independent OPO SACs*—(1) *Non-renal SAC.* An IOPO establishes non-renal SACs based on its costs of procuring non-renal organs for each organ type, by—

(i) Estimating the reasonable and necessary costs it expects to incur for services furnished to procure cadaveric donor non-renal organs during the IOPO's cost reporting period; and

(ii) Dividing the amount estimated in paragraph (c)(1)(i) of this section by the projected number of cadaveric donor non-renal organs the IOPO expects to procure within its cost reporting period.

(2) *Kidney SAC.* (i) An IOPO's Medicare contractor establishes the kidney SAC based on an estimate of the reasonable and necessary costs the IOPO expects to incur to procure cadaveric kidneys during the IOPO's cost reporting period, divided by the projected number of usable cadaveric kidneys the IOPO expects to procure.

(ii) The Medicare contractor develops the IOPO's initial kidney SAC based on the IOPO's budget information.

(iii) The kidney SAC for subsequent years is computed using the IOPO's costs related to kidney acquisition that were incurred in the prior cost reporting period and dividing those costs by the number of usable cadaveric kidneys procured during that cost reporting period. These SACs are the basis for the interim payments by the transplant hospital to the IOPO, as set forth in § 413.420(d).

(iv) The IOPO's Medicare contractor may adjust the kidney SAC during the year, if necessary, for cost changes.

(v) The IOPO cannot use or change its kidney SAC without the contractor's approval.

(3) *Billing SACs for organs generally.* The IOPO uses its own organ SAC and not the SAC it paid to another IOPO when billing a transplant hospital receiving the organ. When an IOPO receives an organ from another IOPO, the receiving IOPO is responsible for paying the procuring IOPO's SAC.

§ 413.406 Acquisition of pancreata for islet cell transplant.

(a) Medicare only covers and pays for reasonable costs of acquisition of pancreata for islet cell transplants into Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial of islet cell transplantation.

(b) Pancreata procured for covered islet cell transplants must be assigned a full standard acquisition charge and be treated as solid organs for procurement purposes.

§ 413.408 Counting of organs for transplant hospitals/hospital-based organ procurement organizations and calculation of Medicare's share of organ acquisition costs.

(a) *Counting and reporting of Medicare usable organs.* THs/HOPOs, must accurately count and report the Medicare usable organs and total usable organs on their Medicare hospital cost reports to ensure that costs to acquire Medicare usable organs are accurately allocated to Medicare.

(b) *Medicare usable organs.* For cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, Medicare usable organs include only the following:

(1) Organs transplanted into Medicare beneficiaries (including kidneys for Medicare Advantage beneficiaries for dates of service on or after January 1, 2021).

(2) Organs for which Medicare has a secondary payer liability for the organ transplant.

(3) Pancreata procured for the purpose of acquiring pancreatic islet cells acquired for transplantation for Medicare beneficiaries participating in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

(c) *Total usable organs.* For cost reporting periods beginning on or after October 1, 2021, for THs/HOPOs, total usable organs include all of the following:

(1) Medicare usable organs.

(2) Organs excised with the intention to be used for research.

(3) Organs excised and either transplanted or furnished to other transplant hospitals or OPOs.

(4) Organs obtained from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs.

(5) Organs sent to veterans' hospitals or organs sent outside the United States.

(6) Organs transplanted into non-Medicare beneficiaries.

(7) Organs for which the transplant was totally or partially paid by primary insurance other than Medicare.

(8) Organs for which the transplant was covered by a Medicare Advantage plan for dates of service prior to January 1, 2021.

(9) Kidneys sent to United States MRTCs with or without contractor-approved a reciprocal sharing agreement with the HOPO in effect prior to March 3, 1988.

(10) Pancreata procured for the purpose of acquiring pancreatic islet cells for transplantation into participants in a National Institute of Diabetes and Digestive and Kidney Diseases clinical trial.

(d) *TH/HOPO's total costs exclude procurement costs of organs sent to foreign transplant centers and organs transplanted into non-Medicare beneficiaries.* A TH/HOPO's total costs for all organs are reduced by the costs associated with procuring organs sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries. THs/HOPOs must separate costs for procuring organs that are sent to foreign transplant centers and organs transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final cost settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in § 413.408(e).

(e) *Calculation of Medicare's share of organ acquisition costs.* For cost reporting periods beginning on or after October 1, 2021, Medicare's share of organ acquisition costs for a TH/HOPO is calculated by multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs (as specified in § 413.408(b)), to total usable organs (as specified in § 413.408(c)).

§ 413.410 Counting of kidneys for independent organ procurement organizations and calculation of Medicare's share of kidney acquisition costs.

(a) *Counting and reporting of the number of usable kidneys.* IOPOs must accurately count and report Medicare usable kidneys and total usable kidneys on their Medicare OPO cost reports to ensure that costs to acquire Medicare usable kidneys are accurately allocated to Medicare.

(b) *Medicare usable kidneys.* For cost reporting periods beginning on or after October 1, 2021, for IOPOs, Medicare usable kidneys include only kidneys sent to transplant hospitals, HOPOs and other IOPOs that are transplanted into Medicare beneficiaries.

(c) *Total usable kidneys.* For cost reporting periods beginning on or after October 1, 2021, for IOPOs, total usable kidneys include all of the following:

(1) Medicare usable kidneys.

(2) Kidneys procured with the intention to be used for research.

(3) Kidneys procured and furnished to other transplant hospitals or OPOs.

(4) Kidneys procured from another OPO or transplant hospital and either transplanted or furnished to other transplant hospitals or OPOs.

(5) Kidneys sent to veterans' hospitals or organs sent outside the United States.

(6) Kidneys for which the transplant was covered by a Medicare Advantage plan for dates of service prior to January 1, 2021.

(7) Kidneys sent to United States MRTCs with or without a contractor-approved reciprocal sharing agreement with the IOPO in effect prior to March 3, 1988.

(d) *IOPO's total costs exclude procurement costs of kidneys sent to foreign transplant centers and organs transplanted into non-Medicare beneficiaries.* (1) An IOPO's total costs for all kidneys is reduced by the costs associated with procuring kidneys that are sent to foreign transplant centers or transplanted in patients other than Medicare beneficiaries.

(2) IOPOs must separate costs for procuring kidneys that are sent to foreign transplant centers and kidneys transplanted in patients other than Medicare beneficiaries from Medicare allowable costs prior to final settlement by the Medicare contractors. The separation of cost is achieved using the Medicare ratio set forth in § 413.410(e).

(e) *Calculation of Medicare's share of kidney acquisition costs.* For cost reporting periods beginning on or after October 1, 2021, Medicare's share of kidney acquisition costs for an IOPO is calculated by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys, as specified in § 413.410(b), to total kidneys, as specified in § 413.410(c).

§ 413.412 Intent to transplant, and counting en bloc, research, and discarded organs.

(a) *Principle of intent to transplant.* (1) For organ acquisition payment purposes, an organ is intended for transplant when the OPO or transplant hospital designates it for transplant prior to the time the donor enters the hospital's operating room for surgical excision/recovery of the organ(s).

(2) OPOs and transplant hospitals must identify the costs associated with the recovered and unrecovered organs and apportion those costs to the appropriate cost centers by organ type.

(b) *Counting en bloc organs.* En bloc organs can be en bloc lungs or en bloc kidneys. For Medicare cost allocation purposes, OPOs and transplant hospitals count—

(1) En bloc lungs or en bloc kidneys procured and transplanted en bloc (two organs transplanted as one unit) as one total usable organ. En bloc organs transplanted into a Medicare beneficiary count as one Medicare usable organ in accordance with § 413.408(b) or one Medicare usable kidney in accordance with § 413.410(b).

(2) En bloc lungs and en bloc kidneys procured en bloc but separated and transplanted into two different recipients as two total usable organs. For each organ transplanted into a Medicare beneficiary, count each as one Medicare usable organ in accordance with § 413.408(b) or one Medicare usable kidney in accordance with § 413.410(b).

(c) *Counting of research organs.* For Medicare cost allocation purposes, organs used for research are not counted as Medicare usable organs in Medicare's share of organ acquisition costs (except pancreata in accordance with § 413.408(b)(3)).

(1) OPOs and transplant hospitals—

(i) Do not count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as Medicare usable organs; and

(ii) Count organs designated for research activities prior to the time the donor entered the hospital's operating room for surgical removal of the organs as total usable organs.

(2) Do not count organs designated for transplant prior to the time the donor entered the hospital's operating room for surgical removal of the organs but subsequently determined to be unusable and donated to research, as Medicare usable organs or total usable organs.

(d) *Counting of discarded/unusable organs.* An organ is not counted as a Medicare usable organ or a total usable organ if the excising surgeon determines, upon initial inspection or after removal of the organ, that the organ is not viable and not medically suitable for transplant and the organ is determined to be unusable and discarded. This includes organs that are determined to be unusable and subsequently donated to research in accordance with paragraph (c)(2) of this section.

§ 413.414 Medicare secondary payer and organ acquisition costs.

(a) *General principle.* If a Medicare beneficiary has a primary health insurer other than Medicare and that primary health insurer has primary liability for the transplant and organ acquisition costs, the Medicare Program may share a liability for organ acquisition costs as a secondary payer in certain instances. To determine whether Medicare has liability as a secondary payer, it is necessary to review the transplant hospital's agreement with the primary insurer.

(b) *Medicare has no secondary payer liability for organ acquisition costs.* If the primary insurer's agreement requires the transplant hospital to accept the primary insurer's payment as payment in full for the transplant and the associated organ acquisition costs, Medicare has zero liability as a secondary payer with no payment obligation for the transplantation costs or the organ acquisition costs, and the organ at issue is not a Medicare usable organ.

(c) *Medicare may have secondary payer liability for organ acquisition costs.* When the primary insurer's agreement does not require the transplant hospital to accept the payment from the primary insurer as payment in full, and the payment the transplant hospital receives from the primary insurer for the transplant and organ acquisition costs is insufficient to cover the entire cost, Medicare may have a secondary payer liability for the organ acquisition costs.

(1) To determine whether Medicare has a secondary payer liability for the organ acquisition costs, it is necessary for the transplant hospital to submit a bill to its Medicare contractor and to compare the total cost of the transplant, including the transplant DRG amount and the organ acquisition costs, to the payment received from the primary payer.

(2) If the payment from the primary payer is greater than the cost of the transplant DRG and the organ acquisition costs, there is no Medicare liability and the transplant hospital must not count the organ as a Medicare usable organ.

(3) If the payment from the primary payer is less than the transplant DRG and the organ acquisition costs, there is a Medicare secondary payer liability and all of the following must occur:

(i) The transplant hospital must pro-rate the payment from the primary payer between the transplant DRG payment and the organ acquisition payment.

(ii) The transplant hospital counts the organ as a Medicare usable organ.

(iii) The portion of the payment applicable to organ acquisition is used on the cost report to reduce the Medicare organ acquisition costs.

§ 413.416 Organ acquisition charges for kidney-paired exchanges.

(a) *Initial living donor evaluations.* When a recipient and donor elect to participate in a kidney paired exchange, the costs of the initial living donor evaluations are incurred by the originally intended recipient's

transplant hospital, regardless of whether the living donor actually donates to their originally intended recipient, a kidney paired exchange recipient, or does not donate at all.

(b) *Additional tests after a match.* In a kidney paired exchange, regardless of whether an actual donation occurs, once the donor and recipient are matched, any additional tests requested by the recipient's transplant hospital and performed by the donor's transplant hospital, are billed to the recipient's transplant hospital as charges reduced to cost (using the donor's transplant hospital's cost to charge ratio) and included as acquisition costs on the recipient transplant hospital's Medicare cost report.

(c) *Procurement and transport of a kidney.* When a donor's transplant hospital procures and sends a kidney to a recipient's transplant hospital all of the following are applicable:

(1) All costs must be reasonable and necessary.

(2)(i) The donor's transplant hospital bills the recipient's transplant hospital.

(ii) The donor's transplant hospital bills its charges reduced to cost, or bills its applicable kidney SAC for the reasonable costs associated with procuring, packaging, and transporting the kidney.

(3) The donor's transplant hospital records the costs described in paragraph (c)(2)(ii) of this section on its Medicare cost report as kidney acquisition costs and offsets any payments received from the recipient's transplant hospital against its kidney acquisition costs.

(4) The recipient's transplant hospital records as part of its kidney acquisition costs—

(i) The amounts billed by the donor's transplant hospital for the reasonable costs associated with procuring, packaging, and transporting the organ; and

(ii) Any additional testing performed and billed by the donor's transplant hospital.

(d) *Donor's procurement occurs at recipient transplant hospital.* In a kidney-paired exchange—

(1) When a donor's transplant hospital does not procure a kidney, but the donor travels to the recipient's transplant hospital for the organ procurement, the reasonable costs associated with the organ procurement are included on the Medicare cost report of the recipient's transplant hospital; and

(2) The travel expenses of the living donor are not allowable Medicare costs.

§ 413.418 Donor community hospitals' charges to organ procurement organizations for organ acquisition costs.

(a) *General.* A donor community hospital (a Medicare-certified non-transplant hospital) incurs organ acquisition costs for donor organ procurement services, authorized by the OPO following declaration of death and consent to donate.

(b) *Donor community hospitals.* For cost reporting periods beginning on or after October 1, 2021, when a donor community hospital incurs costs for services furnished to a cadaveric donor, as authorized by the OPO, the donor community hospital must bill the OPO its customary charges that are reduced to cost by applying its most recently available hospital specific cost-to-charge ratio for the period in which the service was rendered.

§ 413.420 Payment to independent organ procurement organizations and histocompatibility laboratories for kidney acquisition costs.

(a) *Principle.* (1) Covered services furnished after September 30, 1978, by OPOs and histocompatibility laboratories in connection with kidney acquisition and transplantation are reimbursed under the principles for determining reasonable cost contained in this part.

(2) Services furnished by IOPOs and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, are paid directly by the transplant hospital using a kidney SAC (for an IOPO) or contractor-established rates (for a histocompatibility laboratory). (The reasonable costs of services furnished by HOPOs or laboratories are reimbursed in accordance with the principles contained in §§ 413.60 and 413.64.)

(b) *Definitions.* Definitions relevant to this section can be found in § 413.400 of this subpart.

(c) *Agreements with IOPOs and laboratories.* (1) Any IOPO or histocompatibility laboratory that wishes to have the cost of its pre-transplant services reimbursed under the Medicare program must file an agreement with CMS under which the IOPO or laboratory agrees to do all of the following:

(i) To file a cost report in accordance with § 413.24(f) within 5 months following the close of the period covered by the report.

(ii) To permit CMS to designate a contractor to determine the interim reimbursement rate payable by the transplant hospitals for services provided by the IOPO or laboratory and to make a determination of reasonable cost based upon the cost report filed by the IOPO or laboratory.

(iii) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate.

(iv) To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the IOPO or laboratory.

(v) Not to charge any individual for items or services for which that individual is entitled to have payment made under section 1861 of the Act.

(2) The initial cost report due from an IOPO or laboratory is for its first fiscal year during any portion of which it had an agreement with the Secretary under paragraphs (c)(1) and (2) of this section. The initial cost report covers only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Transplant hospitals with approved kidney transplant programs pay the IOPO or histocompatibility laboratory for their pre-transplantation services on the basis of an interim rate established by the contractor for that IOPO or laboratory.

(2) The interim rate is based on a kidney SAC or contractor established rates, associated with procuring a kidney for transplantation, incurred by an IOPO or laboratory respectively, during its previous fiscal year. If there is not adequate cost data to determine the initial interim rate, the Medicare contractor determines it according to the IOPO's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made by transplant hospitals on the basis of interim rates are reconciled directly with the IOPO or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all IOPOs and histocompatibility laboratories must be disseminated to all transplant hospitals and contractors.

(e) *Retroactive adjustment*—(1) *Cost reports.* Information provided in cost reports by IOPOs and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in § 413.24. These cost reports must provide the following:

(i) A complete accounting of the cost incurred by the IOPO or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services.

(ii) Any other data necessary to enable the contractor to make a determination of the reasonable cost of covered

services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by an IOPO or histocompatibility laboratory is reviewed by the contractor and a new interim reimbursement rate for kidney acquisition costs for the subsequent fiscal year is established based upon this review.

(i) A retroactive adjustment in the amount paid under the interim rate is made in accordance with § 413.64(f).

(ii) If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment is made directly between that contractor and the IOPO or laboratory.

(f) *Payment requirements.* For services furnished on or after April 1, 1988, no payment may be made for services furnished by an IOPO that does not meet the requirements of part 486, subpart G, of this chapter.

(g) *Appeals.* If the amount in controversy is $1,000 or more, any IOPO or histocompatibility laboratory that disagrees with a contractor's cost determination under this section is entitled to a contractor hearing, in accordance with the procedures set forth in §§ 405.1811 through 405.1833 of this chapter.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 38. The authority for Part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 39. Section 425.600 is amended by—
■ a. Redesignating paragraph (a)(4)(i)(B)(*2*)(*iv)* as paragraph (a)(4)(i)(B)(*2*)(*v);*
■ b. Adding new paragraph (a)(4)(i)(B)(*2*)(*iv*); and
■ c. In paragraph (a)(4)(i)(B)(*3*), removing the phrase ''paragraph (a)(4)(i)(B)(*2*)(*iii*)'' and adding in its place the phrase ''paragraph (a)(4)(i)(B)(*2*)(*v*).''

The addition reads as follows:

§ 425.600 Selection of risk model.

(a) * * *
(4) * * *
(i) * * *
(B) * * *
(*2*) * * *

(*iv*) Exception for ACOs participating in the BASIC track's glide path that elect to maintain their participation level for performance year 2022. Prior to the automatic advancement for performance year 2022, an ACO that is participating in the BASIC track's glide path for performance year 2021 may elect to remain in the same level of the BASIC track's glide path in which it participated during the 2021 performance year, for performance year 2022. For performance year 2023, the ACO is automatically advanced to the level of the BASIC track's glide path to which the ACO would have automatically advanced absent the election to maintain its participation level for performance year 2022 and, if applicable, the election to maintain its participation level for performance year 2021 under paragraph (a)(4)(i)(B)(*2*)(*iii*) of this section, unless the ACO elects to transition to a higher level of risk and potential reward within the BASIC track's glide path as provided in § 425.226(a)(2)(i). A voluntary election by an ACO under this paragraph must be made in the form and manner and by a deadline established by CMS.

* * * * *

PART 455—PROGRAM INTEGRITY: MEDICAID

■ 40. The authority citation for Part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 41. Section 455.410 is amended by adding paragraph (d) to read as follows:

§ 455.410 Enrollment and screening of providers.

* * * * *

(d) The State Medicaid agency must allow enrollment of all Medicare-enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing (as defined in section 1905(p)(3) of the Act) if the providers or suppliers meet all Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This paragraph (d) applies even if the Medicare-enrolled provider or supplier is of a type not recognized by the State Medicaid Agency.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 42. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 43. Section 495.4 is amended by—
■ a. Adding paragraphs (2)(vii) and (viii) and (3)(vii) and (viii) to the definition of ''EHR reporting period for a payment adjustment year''; and
■ b. Revising the introductory text and paragraph (1) of the definition of ''Meaningful EHR user''.

The additions and revisions read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(vii) The following are applicable for 2023:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2024 and 2025 payment adjustment years. For the FY 2024 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2023.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2025 payment adjustment year.

(viii) The following are applicable for 2024:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2025 and 2026 payment adjustment years. For the FY 2025 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2024.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2026 payment adjustment year.

(3) * * *

(vii) The following are applicable for 2023:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2023 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2023 payment adjustment year.

(viii) The following are applicable for 2024:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR

user in a prior year, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2024 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2024 payment adjustment year.

* * * * *

Meaningful EHR user means all of the following:

(1) Subject to paragraph (3) of this definition, an EP, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year—

(i) Demonstrates in accordance with § 495.40 meaningful use of certified EHR technology by meeting the applicable objectives and associated measures under §§ 495.20, 495.22, 495.24; (ii) Does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT;

(iii) Engages in activities related to supporting providers with the performance of CEHRT; and

(iv) Successfully reports the clinical quality measures selected by CMS to CMS or the States, as applicable, in the form and manner specified by CMS or the States, as applicable.

* * * * *

■ 44. Section 495.24 is amended by—

■ a. Revising paragraph (e)(1)(i) and (e)(4)(ii);

■ b. Adding paragraph (e)(4)(iv);

■ c. Revising paragraphs (e)(5)(ii)(B), (e)(5)(iii)(B), and (e)(6)(ii) introductory text;

■ d. Adding paragraph (e)(6)(ii)(C);

■ e. In paragraph (e)(7)(ii) introductory text, removing the en dash and adding in its place ''all of the following:'';

■ f. In paragraph (e)(7)(ii)(A), by removing ''; and'' and adding in its place a period;

■ g. In paragraph (e)(7)(ii)(B), by removing the sentence ''This measure is worth up to 40 points beginning in CY 2019.'';

■ h. Adding paragraph (e)(7)(ii)(C); and

■ i. Revising paragraphs (e)(8)(ii) introductory text, (e)(8)(ii)(A), (e)(8)(iii) introductory text, and (e)(8)(iii)(A), (D), and (E).

The revisions and additions read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(e) * * *

(1) * * *

(i) Except as specified in paragraph (e)(2) of this section, eligible hospitals and CAHs must do all of the following as part of meeting the definition of a meaningful EHR user under § 495.4:

(A) Meet all objectives and associated measures of the Stage 3 criteria specified in this paragraph (e).

(B) In 2019, 2020, and 2021, earn a total score of at least 50 points.

(C) In 2022 and subsequent years, earn a total score of at least 60 points.

* * * * *

(4) * * *

(ii) *Measure scoring.* Eligible hospitals and CAHs are required to report on the security risk analysis measure in paragraph (e)(4)(iii) of this section, but no points are available for this measure. In 2022 and subsequent years, eligible hospitals and CAHs are required to report on the SAFER Guides measure in paragraph (e)(4)(iv) of this section, but no points are available for this measure.

* * * * *

(iv) *SAFER Guides measure.* Conduct an annual self- assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs.

* * * * *

(5) * * *

(ii) * * *

(B) In 2020 and subsequent years, eligible hospitals and CAHs must meet the e-Prescribing measure in paragraph (e)(5)(iii)(A) of this section, and have the option to report on the query of PDMP measure in paragraph (e)(5)(iii)(B) of this section.

(*1*) In 2020 and 2021, the electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 15 points.

(*2*) In 2022, the electronic prescribing objective in paragraph (e)(5)(i) of this section is worth up to 20 points.

(iii) * * *

(B) Query of prescription drug monitoring program (PDMP) measure. Subject to paragraph (e)(3) of this section, for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law. This measure is worth—

(*1*) 5 bonus points in CYs 2019, 2020, and 2021; and

(*2*) 10 bonus points in CY 2022.

* * * * *

(6) * * *

(ii) *Measures.* For CYs 2019, 2020, and 2021, eligible hospitals and CAHs must meet both of the measures specified in paragraphs (e)(6)(ii)(A) and (B) of this section (each worth up to 20 points). For CY 2022, eligible hospitals and CAHs either must meet both of the measures specified in paragraphs (e)(6)(ii)(A) and (B) of this section (each worth up to 20 points) or must meet the measure specified in paragraph (e)(6)(ii)(C) of this section (worth 40 points).

* * * * *

(C) *Health information exchange (HIE) bi-directional exchange measure.* Subject to paragraph (e)(3) of this section, the eligible hospital or CAH must attest to the following:

(*1*) Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.

(*2*) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners.

(*3*) Using the functions of CEHRT to support bi-directional exchange with an HIE.

* * * * *

(7) * * *

(ii) * * *

(C) Beginning in 2022, the eligible hospital or CAH ensures the patient's health information, with an encounter date on or after January 1, 2016, is available for the patient (or patient-authorized representative) to access indefinitely and using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital or CAHs CEHRT.

(8) * * *

(ii) *Measures.* For CYs 2019, 2020, and 2021, eligible hospitals and CAHs could receive a total of 10 points for the objective under paragraph (e)(8)(i) of this section. In order to meet the objective under paragraph (e)(8)(i) of this section, an eligible hospital or CAH must meet any two measures specified in paragraphs (e)(8)(ii)(A) through (F) of this section. For CY 2022 and subsequent years, eligible hospitals and CAHs could receive a total of 15 points for the objective under paragraph (e)(8)(i) of this section. In order to meet the objective under paragraph (e)(8)(i) of this section and receive 10 points, an

eligible hospital or CAH must meet each of the four measures specified in paragraphs (e)(8)(ii)(A), (B), (C), and (F) of this section. An eligible hospital or CAH will receive a bonus of 5 points for this objective if they meet one of the measures specified in paragraph (e)(8)(ii)(D) or (E).

(A) *Syndromic surveillance reporting measure.* For CYs 2019, 2020, and 2021, the eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. For CY 2022 and subsequent years, the eligible hospital or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency department setting (POS 23).

* * * * *

(iii) *Exclusions in accordance with paragraph (e)(2) of this section.* For CYs 2019, 2020, and 2021, if an exclusion is claimed under paragraphs (e)(8)(iii)(A) through (F) of this section for each of the two measures selected for reporting, the 10 points for the objective specified in paragraph (e)(8)(i) of this section will be redistributed to the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section. For CY 2022 and subsequent years, if an exclusion is claimed under paragraphs (e)(8)(iii)(A) through (F) of this section for each of the four measures required for reporting, the 10 points for the objective specified in paragraph (e)(8)(i) of this section will be redistributed to the provide patients electronic access to their health information measure under paragraph (e)(7)(ii) of this section.

(A) * * *

(*1*) For CYs 2019, 2020 and 2021, does not have an emergency or urgent care department.

(*2*) For CY 2022 and subsequent years, does not have an emergency department.

* * * * *

(D)(*1*) For CYs 2019, 2020, and 2021, any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the public health registry reporting measure specified in paragraph (e)(8)(ii)(D) of this section if the eligible hospital or CAH:

(*i*) Does not diagnose or directly treat any disease or condition associated with a public health registry in its jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no public health agency is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no public health registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*2*) For CY 2022 and subsequent years, the exclusions specified in paragraph (D)(*1*) of this paragraph are no longer available.

(E)(*1*) For CYs 2019, 2020, and 2021, any eligible hospital or CAH meeting at least one of the following criteria may be excluded from the clinical data registry reporting measure specified in paragraph (e)(8)(ii)(E) of this section if the eligible hospital or CAH:

(*i*) Does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

(*ii*) Operates in a jurisdiction for which no clinical data registry is capable of accepting electronic registry transactions in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period.

(*iii*) Operates in a jurisdiction where no clinical data registry for which the eligible hospital or CAH is eligible has declared readiness to receive electronic registry transactions as of 6 months prior to the start of the EHR reporting period.

(*2*) For CY 2022 and subsequent years, the exclusions specified in paragraph (E)(*1*) of this paragraph are no longer available.

* * * * *

■ 45. Section 495.40 is amended by revising paragraphs (b) introductory text and (b)(2)(i)(I) introductory text and adding paragraph (b)(2)(i)(J) to read as follows:

§ 495.40 Demonstration of meaningful use criteria.

* * * * *

(b) *Demonstration by eligible hospitals and CAHs.* An eligible hospital or CAH must demonstrate that it satisfies each of the applicable objectives and associated measures under § 495.20, § 495.22, or § 495.24; supports health information exchange and the prevention of health information blocking or does not take actions to limit or restrict the compatibility or interoperability of CEHRT, as applicable for the EHR reporting period; and engages in activities related to supporting providers with the performance of CEHRT.

(2) * * *

(i) * * *

(I) Support for health information exchange and the prevention of information blocking. For an EHR reporting period in CYs 2017 through 2021, the eligible hospital or CAH must attest that it—

* * * * *

(J) Actions to limit or restrict the compatibility or interoperability of CEHRT. For an EHR reporting period in CY 2022 and subsequent years, the eligible hospital or CAH must attest that it did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of certified EHR technology.

* * * * *

Dated: *April 23, 2021.*

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2021, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2021

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2022 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2022. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would be effective for cost reporting periods beginning on or after October 1, 2021.

In addition, we are setting forth a description of the methods and data we used to determine the proposed LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2022.

In general, except for SCHs and MDHs, for FY 2022, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.G. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As discussed in section IV.A.2 of the preamble of this proposed rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2022. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2022. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2022. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2022. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2022

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2022.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2022, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.A. of the preamble of this proposed rule for a complete discussion on the proposed FY 2022 inpatient hospital update. The table that follows shows these four scenarios:

PROPOSED **FY 2022 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS**				
FY 2022	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Proposed Market Basket Rate-of-Increase	2.5	2.5	2.5	2.5
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.625	-0.625
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.875	0	-1.875
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**0.425**	**1.675**	**-0.2**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful

EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user (as defined in section 1886(n)(3) of the Act) and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket update, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66 ⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674). (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2020 budget neutrality factor and applying a revised factor.
- A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Public Law 114–255), are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.N. of the preamble of this proposed rule).
- An adjustment to remove the FY 2021 outlier offset and apply an offset for FY 2022, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2022, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2022 wage index for the rural floor.

For FY 2022, we are proposing to not remove the FY 2021 Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032–59033). When cost report data regarding reasonable cost of acquisition become available, we intend to consider using that reasonable cost data in future rulemaking for budget neutrality.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2022, we are proposing to rebase and revise the national labor-related and nonlabor-related shares (based on the proposed 2018-based hospital market basket discussed in section IV.B.3. of the preamble of this proposed rule). Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2022, as discussed in section IV.B.3.of the preamble of this proposed rule, we are proposing to use a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we are proposing to calculate the FY 2022 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are proposing to use the proposed 2018-based IPPS operating and capital market baskets for FY 2022. As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2022 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket) by the MFP adjustment, as discussed elsewhere in this proposed rule.

Based on IGI's fourth quarter 2020 forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the forecast of the hospital market basket increase for FY 2022 for this proposed rule is 2.5 percent. As discussed earlier, for FY 2022, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the FY 2022 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four

possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2022 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2022 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

As discussed in section I.F of the preamble of this proposed rule, we are proposing to use alternative data for the FY 2022 ratesetting in situations where the latest data available that would typically be used for the proposed rule is significantly impacted by the COVID–19 PHE. We refer the reader to section I.F of the preamble of this proposed rule for further discussion of this proposal and our analysis of the best available data for purposes of FY 2022 ratesetting. In this section, we discuss the data we are proposing to use for our FY 2022 ratesetting process for the modeling of payments for the budget neutrality factors and the outlier fixed-loss cost threshold.

• Ordinarily, the best available MedPAR data for our ratesetting process would be the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. For FY 2022, under ordinary circumstances, the best available data to model payments for FY 2022 and calculate the budget neutrality adjustments described in this section would be the FY 2020 MedPAR file (discharges on or after October 1, 2019 through discharges on or before September 30, 2020). However, for the reasons discussed in section I.F of this proposed rule, we are proposing to instead use the FY 2019 MedPAR claims data, including for purposes of calculating the proposed budget neutrality adjustments and proposed outlier fixed-loss cost threshold. As discussed in section I.F, we are also soliciting comments on an alternative to this proposal of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, which we may consider finalizing for FY 2022 based on consideration of comments received.

• The inpatient Provider Specific File (PSF) is maintained by the Medicare Administrative Contractor and contains information about data specific to the provider that affects computations for the IPPS. Typically, for the IPPS ratesetting, to model payments, we use the most recent available data at the time of the development of the proposed and final rules, which is typically from the December update of the PSF for the proposed rule and the March update of the PSF for the final rule. For example, for the FY 2022 rulemaking, the PSF we would typically use for the FY 2022 proposed rule would be the December 2020 update of the PSF and the PSF we would typically use for the final rule would be the March 2021 update of the PSF. The fields used from the PSF in our ratesetting are listed in the impact file posted with each proposed and final rule, which includes provider-specific information such as CCRs, bed size, and Medicaid utilization ratio. For some IPPS hospitals, the provider data for these fields in the December 2020 update of the PSF may have come from cost reports that ended during the COVID–19 PHE, and therefore we believe these fields may be affected by the PHE. For FY 2022, in general, we are proposing to use the March 2020 update of the PSF, the latest update of the PSF prior to the PHE, except for those fields on the PSF not affected by the PHE, such as provider-type. For those fields on the PSF that we believe were not impacted by the PHE, we are proposing to use the December 2020 update of the PSF, consistent with our typical process. In the FY 2022 proposed rule impact file, we have indicated which PSF update the applicable fields were sourced from. As discussed in section I.F of this proposed rule, we are also soliciting comments on an alternative approach of using the same data that we would ordinarily use for purposes of the FY 2022 rulemaking, which we may consider finalizing for FY 2022 based on consideration of comments received. In order to facilitate comments on this alternative approach, we are making available supporting data files, such as budget neutrality factors based on the FY 2020 MedPAR file and related MS–DRG relative weighting factors. The supplemental data files can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We include in a supplemental data file the following: budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach.

The methodology we used to calculate the proposed FY 2022 standardized amount is as follows:

• To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

• As in the past, we are proposing to adjust the FY 2022 standardized amount to remove the effects of the FY 2021 geographic reclassifications and outlier payments before applying the FY 2022 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2022 payment policies.

• We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are proposing to remove organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a

pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are proposing to not remove revenue center 891 charges from MS–DRG 018 claims during ratesetting, because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

• For FY 2022 and subsequent fiscal years, we are proposing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835–58842).

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals would continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2022, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029–59030), we are proposing to include all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, we also are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2022, we are proposing to continue to apply a proposed proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2022 this would be FY 2021 final adjustment factors from Table 15 of the FY 2021 IPPS/LTCH PPS final rule) and a proposed proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2022 this would be FY 2021 final adjustment factors from Table 16B of the FY 2021 IPPS/LTCH PPS final rule) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply a proxy readmissions payment adjustment factor and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, would be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2022 (as we did for the last 8 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this proposed rule and later in this section, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.G. of the preamble of this proposed rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are proposing to continue to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

• We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2022. Similar to FY 2021, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2022.

• In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2.b. of the preamble of this proposed rule.

a. Proposed Reclassification and Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this proposed rule, we normalized the recalibrated MS–

DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2022 proposed rule, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2021 labor-related share percentages, the FY 2021 relative weights, and the FY 2021 pre-reclassified wage data, and applied the estimated FY 2022 hospital readmissions payment adjustments and estimated FY 2022 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2021 labor-related share percentages, the proposed FY 2022 relative weights, and the FY 2021 pre-reclassified wage data, and applied the estimated FY 2022 hospital readmissions payment adjustments and estimated FY 2022 hospital VBP payment adjustments applied previously. Because this payment simulation uses the FY 2022 relative weights, consistent with our proposal in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2022 relative weights, we are proposing to apply the adjustor for certain MS–DRG 18 cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2022 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2021. Please see the table later in this section setting forth each of the proposed FY 2022 budget neutrality factors.

b. Updated Wage Index—Proposed Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2022, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2022 relative weights and the FY 2021 pre-reclassified wage indexes, applied the FY 2021 labor-related share of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2022 hospital readmissions payment adjustment and the estimated FY 2022 hospital VBP payment adjustment; and
- Aggregate payments using the proposed FY 2022 relative weights and the proposed FY 2022 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2022 of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2022 hospital readmissions payment adjustments and estimated FY 2022 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2021 to FY 2022. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2022 proposed budget neutrality factors.

c. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, as finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42333 through 42336), we excluded the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the calculation of the wage index for rural areas in the State in which the county is located. We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2022, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2022 labor-related share percentage, the proposed FY 2022 relative weights, and the proposed FY 2022 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2022 labor-related share percentage, the proposed FY 2022 relative weights, and the proposed FY 2022 wage data after such reclassifications, and applied the same estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks proposed for FY 2022, and applies the proposed

policies explained in section III. of the preamble of this proposed rule. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the proposed FY 2022 budget neutrality factors.

The proposed FY 2022 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2021 budget neutrality adjustment factor. We note that the proposed FY 2022 budget neutrality adjustment reflects FY 2022 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

As discussed in the interim final rule with comment period titled ''Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)'' (CMS–1762–IFC), publicly available in conjunction with this proposed rule, we amended our regulations at § 412.230 to allow hospitals with a rural redesignation under Section 1886(d)(8)(E) of the Act to reclassify under the MGCRB using the rural reclassified area as the geographic area in which the hospital is located. These regulatory changes aligned our policy with the decision in *Bates County Memorial Hospital* v. *Azar,* 464 F. Supp. 3d (D.D.C. 2020). For FY 2022, there are approximately 22 hospitals that may, as a result of the settlement or other resolution of pending litigation, receive a higher wage index than they might otherwise have received based on the information currently available to us. If these hospitals do receive higher wage indexes for that reason, we intend to include any amounts they receive by reason of those higher wage indexes in the calculation of the budget neutrality factor, pursuant to our authority at section 1886(d)(8)(D) and 1886(d)(5)(I)(i). For FY 2022, if these hospitals do receive a higher wage index at the time of the final rule than they might otherwise have received, we estimate the FY 2022 budget neutrality adjustment could increase by as much as approximately one-half of a percentage point compared to the budget neutrality adjustment that might otherwise have been calculated.

d. Proposed Rural Floor Proposed Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index. We note, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42332 through 42336), for FY 2022 we are calculating the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103).

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2022, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2021 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2022 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2022 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2019 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor; and
- National simulated payments with the rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the proposed FY 2022 budget neutrality factors.

As further discussed in section III.G.2 of this proposed rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are proposing to apply the imputed floor after the application of the rural floor and would apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. As further explained in section III.G.2 of this proposed rule, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022) into the calculation of the provider wage index for this proposed rule. We will include the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule. We refer the reader to section III.G.2 of the preamble of this proposed rule for a complete discussion regarding the imputed floor.

e. Proposed Rural Community Hospital Demonstration Program Adjustment

In section V.L. of the preamble of this proposed rule, we discuss the Rural Community Hospital Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). We make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We refer readers to section V.M. of the preamble of this proposed rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2022, based on the latest data for this proposed rule, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $63,829,479.00. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2022, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that would be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2022 budget

neutrality factors. We refer readers to section V.L. of the preamble of this proposed rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

f. Continuation of the Low Wage Index Hospital Policy—Proposed Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this proposed rule, we are continuing the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in section III.G.3 of this proposed rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are proposing to make a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this proposed budget neutrality adjustment factor for FY 2022, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2022 labor-related share percentage, the proposed FY 2022 relative weights, and the proposed FY 2022 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy, and applied the estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section; and
- Aggregate payments using the proposed FY 2022 labor-related share percentage, the proposed FY 2022 relative weights, and the proposed FY 2022 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same estimated FY 2022 hospital readmissions payment adjustments and the estimated FY 2022 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

This proposed FY 2022 budget neutrality adjustment factor was applied to the standardized amount.

The following table is a summary of the proposed FY 2022 budget neutrality factors, as discussed in the previous sections.

Summary of Proposed FY 2022 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000098
Wage Index Budget Neutrality Factor	1.000277
Reclassification Budget Neutrality Factor	0.987018
*Rural Floor Budget Neutrality Factor	0.993988
Rural Demonstration Budget Neutrality Factor	0.999412
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998108

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

In order to facilitate comments on the alternative approach discussed in section I.F of this proposed rule of using the same FY 2020 data that we would ordinarily use for purposes of FY 2022 ratesetting, and which we may consider finalizing for FY 2022 based on consideration of comments received, we are making available the budget neutrality and other ratesetting adjustments calculated under this alternative approach, which can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

g. Proposed Adjustment for FY 2022 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2022, we are proposing to implement the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

h. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2022 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2022, we are proposing to incorporate an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm*.

(1) Proposed Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2022 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital would owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS would owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Proposed Projection of Outlier Payment Reconciliations for the FY 2022 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2022, we are proposing to continue to incorporate outlier reconciliation in the FY 2022 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation. For FY 2022, we applied the same methodology finalized in FY 2020, using the historical outlier reconciliation amounts from the FY 2015 cost reports (cost reports with a begin date on or after October 1, 2014, and on or before September 30, 2015).

Similar to the FY 2021 methodology, in this proposed rule, we are proposing to determine a projection of outlier payment reconciliations for the FY 2022 outlier threshold calculation, by advancing the methodology by 1 year. Specifically, we are proposing to use FY 2016 cost reports (cost reports with a begin date on or after October 1, 2015, and on or before September 30, 2016).

For FY 2022, we are proposing to use the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2022 outlier threshold calculation. The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2022:

Step 1.—Use the Federal FY 2016 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2016 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2016 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2016. This percentage amount would be used to adjust the outlier target for FY 2022 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2016 cost reports based on the December 2020 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, we are targeting an amount higher than 5.1 percent for outlier payments for FY 2022 under our proposed methodology.

For this FY 2022 proposed rule, we used the December 2020 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2022 final rule, we propose to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2022, would be the March 2021 extract. Similar to the FY 2021 final rule, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2022 outlier threshold.

For this FY 2022 proposed rule, based on the December 2020 HCRIS, 12 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $12,140,344 (Step 2). The total Federal operating payments based on the December 2020 HCRIS was $88,239,764,644 (Step 3). The ratio (Step 4) is a negative 0.013758 percent, which, when rounded to the second digit, is −0.01 percent. Therefore, for FY 2022, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (−.01 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of the Addendum to this proposed rule, we provide the FY 2022 outlier threshold as calculated

for this proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation.

As explained in the FY 2020 IPPS/LTCH PPS final rule, we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond three decimals). However, under our methodology, we believe a three decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the unrounded six decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we are proposing to determine an outlier adjustment by applying a factor to the standardized amount that accounts for the projected proportion of total estimated FY 2022 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2022 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2022 would be the sum of the estimated FY 2022 outlier payments based on the claims data from the outlier model and the estimated FY 2022 total operating outlier reconciliation dollars. We believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2022 operating Federal payments paid as outliers. In other words, the net effect of our outlier proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2022 outlier payments (which include the proposed estimated recoupment percentage for FY 2022 of 0.01 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the proposed operating outlier offset to the standardized amount is 0.949 (1 − 0.051).

We are inviting public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2022.

(b) Proposed Reduction to the FY 2021 Capital Standard Federal Rate by an Adjustment Factor to Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2022 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2022, we are proposing to use the same methodology from FY 2020 to adjust the FY 2022 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposal for FY 2022 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also are proposing to adjust our estimate of FY 2022 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. To do so, we are proposing to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2022 outlier threshold calculation.

Step 1.—Use the Federal FY 2016 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule. We used the December 2020 HCRIS extract for this proposed rule and expect to use the March 2020 HCRIS extract for the FY 2022 final rule. Similar to the FY 2020 final rule, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2022 adjustment to the FY 2022 capital standard Federal rate.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2016 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2016 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2016. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2022 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we are proposing that the estimate of capital outlier payments for FY 2022 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2022 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

Similarly, for this FY 2022 proposed rule, we used the December 2020 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2022 final rule, we are proposing to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2022, would be the March 2021 extract. As previously noted, we may

also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2022 adjustment to the FY 2022 capital standard Federal rate.

For this FY 2022 proposed rule, the estimated percentage of FY 2022 capital outlier payments otherwise determined using the shared outlier threshold is 5.34 percent (estimated capital outlier payments of $431,821,043 divided by (estimated capital outlier payments of $431,821,043 plus the estimated total capital Federal payment of $7,651,022,484)). Based on the December 2020 HCRIS, 12 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $915,421 (Step 2). The total Federal capital payments based on the December 2020 HCRIS was $7,961,217,741 (Step 3) which results in a ratio (Step 4) of −0.01 percent. Therefore, for FY 2022, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2022 aggregate capital outlier payments by 0.01 percent.

As discussed in section III.A.2. of this Addendum, we are proposing to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2022.

We are inviting public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2022 capital outlier payments for purposes of determining the capital outlier adjustment factor.

(2) Proposed FY 2022 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2022 outlier threshold, we simulated payments by applying proposed FY 2022 payment rates and policies using cases from the FY 2019 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2022 outlier threshold, we inflated the charges on the MedPAR claims by 3 years, from FY 2019 to FY 2022. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are proposing to use the following methodology to calculate the charge inflation factor for FY 2022:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we are proposing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835–58842).
- Because this payment simulation uses the proposed FY 2022 relative weights, consistent with our proposal discussed in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. As discussed in section II.E.2.b. of the preamble of this proposed rule, we are applying a proposed adjustment to account for certain cases that group to MS–DRG 018 in calculating the FY 2022 relative weights and for purposes of budget neutrality and outlier simulations.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year. However, for this FY 2022 proposed rule, we are proposing to use the FY 2019 MedPAR claims data, which is 3 years prior to FY 2022. Therefore, we are proposing to inflate the charges on the MedPAR claims data by 3 years.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change. For the same reasons discussed in that rulemaking, and consistent with our proposal to use the FY 2019 MedPAR for purposes of FY 2022 ratesetting, for FY 2022, we are proposing to use the same methodology as FY 2020, and based on the same data used in the FY 2021 IPPS/LTCH PPS final rule to determine the charge inflation factor for this proposed rule. That is, for FY 2022, we are proposing to use the MedPAR files for the two most recent available Federal fiscal year time periods prior to the COVID–19 PHE to calculate the charge inflation factor. Specifically, for this proposed rule we used the March 2019 MedPAR file of FY 2018 (October 1, 2017 to September 30, 2018) charge data (released for the FY 2020 IPPS/LTCH PPS final rule) and the March 2020 MedPAR file of FY 2019 (October 1, 2018 to September 30, 2019) charge data (released for the FY 2021 IPPS/LTCH PPS final rule) to compute the proposed charge inflation factor. We propose that for the FY 2022 IPPS/LTCH PPS final rule, we would continue to use the charge inflation estimate from the FY 2021 IPPS/LTCH PPS final rule. In addition, we are soliciting comments on the alternative approach of using the same data we would ordinarily use for purposes of FY 2022 ratesetting, as discussed in section I.F of this proposed rule, and note that under this alternative approach, if finalized, we would anticipate using more recently updated data for purposes of the FY 2022 IPPS/LTCH PPS final rule. Under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case for FY 2022, we compared the average covered charge per case of $61,578.82 ($584,618,863,834/9,493,830 cases) from October 1, 2017 through September 31, 2018, to the average

covered charge per case of $65,522.10 ($604,209,834,327/9,221,466 cases) from October 1, 2018 through September 31, 2019. This rate-of-change was 6.4 percent (1.06404) or 20.4 percent over three years. Because we are proposing to use the FY 2019 MedPAR for the FY 2022 ratesetting, we applied a factor of 20.4 percent (1.20469) over 3 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

In order to facilitate comments on the alternative approach discussed in section I.F of this proposed rule of using the same data that we would ordinarily use for purposes of FY 2022 ratesetting, and which we may consider finalizing for FY 2022 based on consideration of comments received, we are making available budget neutrality and other ratesetting adjustments, including the charge inflation factor, calculated under this alternative approach, which can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We include in a supplemental data file the following: Budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach. Consistent with historical practice, if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

As discussed previously, in this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to establish the FY 2022 outlier threshold using hospital CCRs from the March 2020 update to the Provider-Specific File (PSF), which is consistent with our proposed approach of not using data that may have been significantly impacted by the COVID–19 PHE. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2022, we are also proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section).

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Ordinarily, for the proposed rule, we would use CCRs from the December 2020 update of the PSF and apply a proposed adjustment factor to adjust the CCRs from the December 2020 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2020 PSF. However, as discussed previously, we believe the operating and capital CCRs in the December 2020 PSF may be significantly impacted by the PHE. Therefore, we are proposing to adjust the CCRs from the March 2020 update of the PSF (the latest update of the PSF prior to the PHE) by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2019 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2020 update of the PSF. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this would produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for this proposed rule, we calculated a proposed March 2019 operating national average case-weighted CCR of 0.254027 and a proposed March 2020 operating national average case-weighted CCR of 0.247548. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2019 operating national average case-weighted CCR from the March 2020 operating national average case-weighted CCR and then dividing the result by the March 2019 national operating average case-weighted CCR. This resulted in a one-year national operating CCR adjustment factor of 0.974495. Because we are proposing to use CCRs from the March 2020 update of the PSF for FY 2022, we calculated a two-year proposed national operating CCR adjustment by multiplying 0.974495 * 0.974495.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a March 2019 capital national average case-weighted CCR of 0.02073 and a March 2020 capital national average case-weighted CCR of 0.019935. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the March 2019 capital national average case-weighted CCR from the March 2020 capital national average case-weighted CCR and then dividing the result by the March 2019 capital national average case-weighted CCR. This resulted in a one-year national capital CCR adjustment factor of 0.96165. Because we are proposing to use CCRs from the March 2020 update of the PSF for FY 2022, we calculated a two-year proposed national capital CCR adjustment by multiplying 0.96165 * 0.96165.

As discussed in section I.F of this proposed rule and in section I.O of Appendix A of this proposed rule, we are soliciting comments on an alternative approach of using the same data we would ordinarily use for purposes of FY 2022 ratesetting, which we may consider finalizing for FY 2022 based on consideration of comments received, and are making available supplemental data files to facilitate comments on this alternative approach. As noted previously, we include in a supplemental data file the following: Budget neutrality factors, charge inflation factor, the CCR adjustment factors, and outlier threshold based on this alternative approach. Consistent with historical practice, if we were to finalize this alternative approach, we would use the most recent available data for the final rule, as appropriate.

For purposes of estimating the proposed outlier threshold for FY 2022, we used a wage index that reflects the policies discussed in the proposed rule. This includes the proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act, the proposed out-migration adjustment as added by section 505 of Public Law 108–173, as well as incorporating the FY 2022 wage index adjustment for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. If we did not take the aforementioned into account, our estimate of total FY 2022 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation). We note, given the recent enactment of section 9831 of Public Law 117–2 on March 11, 2021, there was not sufficient time available to incorporate the changes required by this statutory provision (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022) into the calculation of the provider wage index for this proposed rule. We will include the imputed floor adjustment in the calculation of the provider wage index in the FY 2022 final rule.

As described in sections V.K. and IV.L., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base

DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2022, we are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2022, we are proposing to include estimated FY 2022 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are proposing to incorporate an estimate of FY 2022 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this FY 2022 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.013758 percent, which, when rounded to the second digit, is -0.01 percent. Therefore, for FY 2022, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent-(−.01 percent)]. Under this proposed approach, we determined a threshold of $30,967 and calculated total outlier payments of $5,081,824,613 and total operating Federal payments of $94,365,941,593. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.11 percent target, which reflects our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $31,027. We are proposing an outlier fixed-loss cost threshold for FY 2022 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $30,967. As discussed further in section I.A of this proposed rule, we note that the estimate of the outlier threshold using the FY 2020 MedPAR file is $36,483.

(3) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2022 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 5.34 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are proposing to reduce the FY 2022 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2022 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.946676

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2022 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III. A. 2 in the Addendum of this proposed rule.

We are proposing to apply the outlier adjustment factors to the FY 2022 payment rates after removing the effects of the FY 2020 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.142 or capital CCRs greater than 0.135, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2021 and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2022 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2020 Outlier Payments

Our current estimate, using available FY 2020 claims data, is that actual outlier payments for FY 2020 were approximately 5.42 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2020, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2020. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2020 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2021 period would not be available until after September 30, 2021, we are unable to provide an estimate of actual outlier payments for FY 2021 based on FY 2021 claims data in this proposed rule. We will provide an estimate of actual FY 2021 outlier payments in the FY 2023 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2022 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2022. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 67.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2022.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2022 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2021 national standardized amounts to the proposed FY 2022 national standardized amounts. The second through fifth columns display the changes from the FY 2021 standardized amounts for each proposed applicable FY 2022 standardized amount. The first row of the table shows the updated (through FY 2021) average standardized amount after restoring the FY 2021 offsets for outlier payments, geographic reclassification, rural demonstration, lowest quartile, and transition budget neutrality. The MS–DRG reclassification and recalibration, wage index, and stem cell acquisition budget neutrality factors are cumulative. Accordingly, those FY 2021 adjustment factors have not been removed from the base rate in the following table. Additionally, for FY 2022 we have applied the budget neutrality factors for the lowest quartile hospital policy, described previously.

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CHANGES FROM FY 2021 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2022 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2022 Base Rate after removing: 1. FY 2021 Geographic Reclassification Budget Neutrality (0.986616) 2. FY 2021 Operating Outlier Offset (0.949) 3. FY 2021 Rural Demonstration Budget Neutrality Factor (0.999626) 4. FY 2021 Lowest Quartile Budget Neutrality Factor (0.99797) 5. FY 2021 Transition Budget Neutrality Factor (0.998851)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04	If Wage Index is Greater Than 1.0000: Labor (67.6%): $ 4,319.35 Nonlabor (32.4%): $ 2,070.22 If Wage Index is less Than or Equal to 1.0000: Labor (62%): $ 3,961.53 Nonlabor (38%): $ 2,428.04
Proposed FY 2022 Update Factor	1.023	1.00425	1.01675	0.998
Proposed FY 2022 MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.000098	1.000098	1.000098	1.000098
Proposed FY 2022 Wage Index Budget Neutrality Factor	1.000277	1.000277	1.000277	1.000277
Proposed FY 2022 Reclassification Budget Neutrality Factor	0.987018	0.987018	0.987018	0.987018
Proposed FY 2022 Rural Demonstration Budget Neutrality Factor	0.999412	0.999412	0.999412	0.999412
Proposed FY 2022 Lowest Quartile Budget Neutrality Factor	0.998108	0.998108	0.998108	0.998108
Proposed FY 2022 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2022 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
Proposed National Standardized Amount for FY 2022 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,150.84** **Nonlabor $1,989.45**	**Labor: $4,074.76** **Nonlabor: $1,952.99**	**Labor: $4,125.48** **Nonlabor: $1,977.30**	**Labor: $4,049.40** **Nonlabor: $1,940.83**
Proposed National Standardized Amount for FY 2022 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,806.98** **Nonlabor: $2,333.31**	**Labor: $3,737.21** **Nonlabor: $2,290.54**	**Labor: $3,783.72** **Nonlabor: $2,319.06**	**Labor: $3,713.94** **Nonlabor: $2,276.29**

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B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the proposed labor related and -nonlabor related- shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2022. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2022, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the FY 2022 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor. For FY 2011 and in prior fiscal years, we used the most recent cost-of-living adjustment (COLA) factors obtained from the U.S. Office of Personnel Management (OPM) website at *https://www.opm.gov/policy-data-oversight/pay-leave/pay-systems/nonforeign-areas/#url=COLA-Rates* to update this nonlabor portion.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51797), we explained that sections 1911 through 1919 of the Nonforeign Area Retirement Equity Assurance Act, as contained in subtitle B of title XIX of the National Defense Authorization Act (NDAA) for Fiscal Year 2010 (Pub. L. 111–84, October 28, 2009), transitions the Alaska and Hawaii COLAs to locality pay. We finalized that, for FY 2012, as OPM transitioned away from COLAs, we would continue to use the same ''frozen'' COLA factors (published by OPM) that we used to adjust payments in FY 2011 (which were based on OPM's 2009 COLA factors) to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. We refer readers to the FY 2012 IPPS/LTCH PPS final rule for a more detailed discussion of our rationale for continuing to use the frozen COLAs in FY 2012.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), for FY 2013, we continued to use the same COLA factors that were used to adjust payments in FY 2012 (as originally used to adjust payments in FY 2011, which were based on OPM's 2009 COLA factors). We also established a methodology to update the COLA factors published by OPM every 4 years (at the same time as the update of the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed rule (77 FR 28145 and 28146) for a detailed description of this methodology. For FY 2014, we updated the COLA factors for Alaska and Hawaii published by OPM for 2009 using the methodology finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701). In the FY 2018 IPPS/LTCH PPS final rule, we again updated the COLA factors using this same methodology (82 FR 38530).

For FY 2022, we are proposing to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Specifically, we are proposing to update the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We note that for the prior update to the COLA factors, we used the growth in the CPI for Anchorage and the CPI for Honolulu. Beginning in 2018, these indexes were renamed to the CPI for Urban Alaska and the CPI for Urban Hawaii due to the BLS updating its sample to reflect the data from the 2010 Decennial Census on the distribution of the urban population (*https://www.bls.gov/regions/west/factsheet/2018cpirevisionwest.pdf*, accessed January 22, 2021). The CPI for Urban Alaska area covers Anchorage and Matanuska-Susitna Borough in the State of Alaska and the CPI for Urban Hawaii covers Honolulu in the State of Hawaii. BLS notes that the indexes are considered continuous over time, regardless of name or composition changes.

Because BLS publishes CPI data for only Urban Alaska and Urban Hawaii, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these urban areas and the United States (as measured by the CPIs mentioned previously) are appropriate proxies for the relative price differences between the ''other areas'' of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Urban Alaska, Urban Hawaii, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share for the proposed 2018-based IPPS market basket is comprised of a different mix of commodities and services. Therefore, we are proposing to create reweighted indexes for Urban Alaska, Urban Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and using the approximate 57 percent commodities/43 percent services shares obtained from the proposed 2018-based IPPS market basket. We created reweighted indexes using BLS data for 2009 through 2020—the most recent data available at the time of this proposed rulemaking. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530), we created reweighted indexes based on the 2014-based IPPS market basket (which was adopted for the FY 2018 IPPS update) and BLS data for 2009 through 2016 (the most recent BLS data at the time of the FY 2018 IPPS/LTCH PPS rulemaking).

We continue to believe this methodology is appropriate because we continue to make a COLA for hospitals located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standardized amount by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2018 IPPS/LTCH PPS final rule ((82 FR 38530), under the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, we are proposing for FY 2022 to continue to use a cap of 25 percent, as our policy is based on OPM's COLA factors (updated by the methodology described previously).

Applying this methodology, the COLA factors that we are proposing to establish for FY 2022 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii are shown in the table in this section. For comparison purposes, we also are showing the FY 2018 COLA factors. We note that the proposed FY 2022 COLA factors for City and County of Honolulu, County of Kauai, and County of Maui and County of Kalawao are a result of applying the 25 percent cap as described previously.

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and

53701), we intend to update the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

Proposed FY 2022 Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Hospitals

Area	FY 2018 through FY 2021	Proposed FY 2022 through FY 2025
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
Rest of Alaska	1.25	1.24
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

C. Calculation of the Proposed Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2022

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2022 equals the Federal rate (which includes uncompensated care payments).

Under current law, the MDH program has been extended for discharges occurring through September 30, 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (which, as discussed in section VI.G. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2022 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for FY 2022 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))
—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)
—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)
—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount
—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)
—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)
—Operating Outlier Payment = (Operating Costs − Operating Outlier Threshold) × Marginal Cost Factor
—Capital Outlier Payment = (Capital Costs − Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the

uncompensated care payment to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted previously, the MDH program has been extended under current law for discharges occurring through September 30, 2022. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2022

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	2.5	2.5	2.5	2.5
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.625	-0.625
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.875	0	-1.875
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**0.425**	**1.675**	**-0.2**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.B. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or an MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2021. We note that, in this proposed rule, for FY 2022, we are not proposing to make a documentation and coding adjustment to the hospital specific-rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2022

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2022, which would be effective for discharges occurring on or after October 1, 2021.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2022

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2022. In particular, we explain why the proposed FY 2022 capital Federal rate would increase approximately 1.22 percent, compared to the FY 2021 capital Federal rate. As discussed in the impact analysis in

Appendix A to this FY 2022 IPPS/LTCH PPS proposed rule, we estimate that capital payments per discharge would increase approximately 0.5 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

As discussed in section I.F of the preamble to this proposed rule, we are proposing to use FY 2019 data for the FY 2022 ratesetting in situations where the FY 2020 data were significantly impacted by the COVID–19 PHE. Ordinarily, for this proposed rule, we would use claims from the FY 2020 MedPAR file for purposes of calculating the budget neutrality adjustment factors for changes resulting from the annual DRG reclassification and recalibration and changes in the GAF. However, as discussed in section I.F of the preamble to this proposed rule, we believe the FY 2020 claims data were significantly impacted by the COVID–19 PHE. Therefore, for the purposes of calculating these budget neutrality adjustment factors for FY 2022, we are proposing to use claims from the March 2020 update of the FY 2019 MedPAR file. Similarly, for this proposed rule, we ordinarily would use provider data from the December 2020 update of the Provider Specific File (PSF) for purposes of calculating these budget neutrality adjustment factors. However, for some IPPS hospitals, the provider data in the December 2020 update of the PSF may have come from cost reports that ended during the COVID–19 PHE, and therefore we believe these data may be affected by the PHE. Therefore, for the purposes of calculating these budget neutrality adjustment factors for FY 2022, we are proposing to use provider data from the March 2020 update of the PSF, which was derived from cost reports ending prior to the COVID–19 PHE, except for those fields on the PSF not affected by the PHE. As discussed previously and in section I.O.1 of Appendix A, we are also considering an alternative approach that would use the FY 2020 data that we ordinarily would use in the FY 2022 IPPS ratesetting. To facilitate comments on this alternative approach, which we may consider finalizing for FY 2022 based on consideration of comments received, we are making available budget neutrality and other ratesetting adjustments calculated under this alternative approach. These data can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2022 under that framework is 0.7 percent based on a projected 1.0 percent increase in the proposed 2018-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of −0.3 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2022 CIPI projection in that same section of this Addendum. In this proposed rule, we describe the policy adjustments that we are proposing to apply in the update framework for FY 2022.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2022, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2022. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, the proposed net adjustment for case-mix change in FY 2022 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this FY 2022 IPPS/LTCH PPS proposed rule, we ordinarily would use the FY 2020 MedPAR claims data to evaluate the effects of the FY 2020 DRG reclassification and recalibration. However, for the reasons discussed in section I.F of the preamble of this proposed rule, we believe the FY 2020 MedPAR claims data were significantly impacted by the COVID–19 PHE. Due to these impacts, we are proposing to not evaluate the effects of the FY 2020 DRG reclassification and recalibration as part of our update for FY 2022. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2022.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of −0.3 percentage point was calculated for the FY 2020 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2020 CIPI (1.5 percent) used in calculating the FY 2020 update factor was not the same percentage increase as the actual realized price increase (1.2 percent). As this exceeds the 0.25 percentage point threshold, we are proposing an adjustment of −0.3 percentage point for the forecast error in the update for FY 2022.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG

system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2022 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2022, we are proposing to use an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2015 and extending through FY 2019. Based on these data, we estimated that case-mix constant intensity declined during FYs 2015 through 2019. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2022. Therefore we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2022.

Earlier, we described the basis of the components we used to develop the proposed 0.7 percent capital update factor under the capital update framework for FY 2022, as shown in the following table.

PROPOSED FY 2022 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.0
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-0.5
Real Across DRG Change	0.5
Subtotal	0.0
Effect of FY 2020 Reclassification and Recalibration**	0.0
Forecast Error Correction	-0.3
Total Proposed Update	0.70

*The capital input price index represents the proposed 2018-based CIPI.

**Due to the impacts of the COVID-19 PHE on the FY 2020 MedPAR claims data, we are proposing to not evaluate the effects of the FY 2020 DRG reclassification and recalibration. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2022.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2022, we are proposing to incorporate the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2021. (For more details on our proposal to incorporate outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this proposed rule.)

For FY 2021, we estimated that outlier payments for capital-related PPS payments would equal 5.34 percent of inpatient capital-related payments based on the capital Federal rate in FY 2021. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 5.34 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2022. However, using the methodology outlined in section II.A. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease FY 2022 aggregate estimated capital outlier payments by 0.01 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.33 percent (5.34 percent − 0.01 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2022. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9467 in determining the capital Federal rate for FY 2022. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2022 would be slightly lower than the percentage for FY 2021.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2022 outlier adjustment of 0.9467 is a 0.01 percent change from the FY 2021 outlier adjustment of 0.9466. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2022 is 1.0001 (0.9467/0.9466) so that the proposed outlier adjustment would increase the FY 2022 capital Federal rate by approximately 0.01 percent compared to the FY 2021 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this proposed rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated that this policy will be effective for at least 4 years, beginning in FY 2020. Therefore, as discussed in section III.G.3 of the preamble of this proposed rule, this policy was applied in FYs 2020 and 2021, and will continue to apply in FY 2022.

In FYs 2020 and 2021, we also placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year (see (84 FR 42336 through 42338) and (85 FR 58753 through 58755), respectively). As discussed in section III.A.2 of the preamble of this proposed rule, we are not proposing to apply this policy in FY 2022.

As we discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42638 through 42639), we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. Specifically, we established a 2-step methodology, under which we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. (We note that in FY 2020 we adopted a policy to calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under § 412.103. We are not proposing to change this policy in FY 2022.) In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index and our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year in FYs 2020 and 2021. In this section, we refer to these two policies as the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases. Although we calculated separate factors for changes to the GAFs under each step of this 2-step methodology, our GAF/DRG budget neutrality factor reflected a single combined GAF budget neutrality factor that accounted for the budget neutrality calculations determined under each step of that methodology.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. In FY 2021, in using the single combined GAF budget neutrality factor that accounted for both steps of our 2-step methodology, we also treated the FY 2020 budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases as a permanent factor and did not remove it from the FY 2021 capital Federal rate. In this proposed rule, we are proposing to no longer permanently apply the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases such that they would not be applied cumulatively in determining the capital Federal rate. We believe this is more technically appropriate because the GAFs with the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases policies applied from the previous year are not used in the budget neutrality factor calculations for the current year. These GAFs are not used because the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases policies (when applicable) are applied after the out-migration and Frontier state adjustments, which are not subject to budget neutrality. Therefore, in order to continue to exclude the out-migration and Frontier state adjustments from budget neutrality, our budget neutrality calculations for permanent factors, as described in more detail later in this section, are determined from aggregate payments calculated using the GAFs from the previous year prior to the application of the out-migration and frontier state adjustment (and by extension the lowest quartile hospital wage index adjustment and 5-percent cap on wage index decreases). As a result, the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases only ensures budget neutrality for the application of those policies within the year, but not for a change in the policy as compared to the prior year. Accordingly and consistent with this proposed approach, prior to calculating the GAF budget neutrality factors for FY 2022, we are proposing to remove from the capital Federal rate the cumulative effect of the budget neutrality factor applied in FYs 2020 and 2021 for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases. Specifically, we are proposing to divide the capital Federal rate by a factor of 0.9927, which accounts for the cumulative effect of the FY 2020 budget neutrality factor of 0.9964 (84 FR 42639) and the FY 2021 budget neutrality factor of 0.9963 (85 FR 59047) ($0.9964 \times 0.9963 = 0.9927$).

In light of the proposed changes to the wage index and the continuation of the lowest quartile hospital wage index adjustment policy in FY 2022 discussed previously, which directly affects the GAF, we are proposing to continue to compute a budget neutrality factor for changes in the GAFs in two steps. We discuss our proposed 2-step calculation of the proposed GAF budget neutrality factors for FY 2022 as follows.

To determine the GAF budget neutrality factors for FY 2022, we first compared estimated aggregate capital Federal rate payments based on the FY 2021 MS–DRG classifications and relative weights and the FY 2021 GAFs to estimated aggregate capital Federal rate payments based on the FY 2021 MS–DRG classifications and relative weights and the proposed FY 2022 GAFs without incorporating the lowest quartile hospital wage index adjustment. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0000 for FY 2022. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2022 GAFs with and without the lowest quartile hospital wage index adjustment. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2022 MS–DRG classifications and relative weights and the proposed FY 2022 GAFs (both with and without the lowest quartile hospital wage index adjustment). (We note, for this calculation the proposed GAFs included the out-migration and Frontier state adjustments. We further note that this calculation will include the imputed floor adjustment in the FY 2022 final rule. As discussed in section III.X. of the preamble of this proposed rule, given the recent enactment of section 9831 of Pub. L. 117–2 on March 11, 2021 (which provides for the application of the imputed floor adjustment in a non-budget neutral manner beginning in FY 2022), there was not sufficient time available to incorporate the imputed floor required by this provision into the calculation of the provider wage index for this proposed rule.) To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment on the proposed FY 2022 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9976. As discussed earlier in this section, we are proposing that the lowest quartile hospital wage index adjustment factor not be permanently built into the capital Federal rate. Consistent with this proposal, and unlike in previous rules, we present the calculated lowest quartile hospital wage index adjustment factor calculated under the second step of this 2-step methodology separately from the other calculated budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the combined proposed GAF/DRG adjustment factor described later in this section.

We compared estimated aggregate capital Federal rate payments based on the FY 2021 MS–DRG classifications and relative weights and the proposed FY 2022 GAFs (without the lowest quartile hospital wage index adjustment) to estimated aggregate capital Federal rate payments based on the proposed FY 2022 MS–DRG classifications and relative weights and the proposed FY 2022 GAFs (without the lowest quartile hospital wage index adjustment). The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 1.0001.

The proposed incremental adjustment factor for proposed MS–DRG classifications and changes in relative weights (1.0001) and for proposed changes in the FY 2022 GAFs due to the proposed update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0000) is 1.0001 (1.0001×1.0000). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment on the FY 2022 GAFs, as described previously, we calculated a proposed budget neutrality adjustment factor of 0.9976 for FY 2022.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification or the lowest quartile hospital wage index adjustment described previously have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 1.0001 accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs that result from proposed updates to the wage data, the effects on the GAFs of FY 2022 geographic reclassification decisions made by the MGCRB compared to FY 2021 decisions, and the application of the rural floor policy. The proposed lowest quartile hospital wage index adjustment factor of 0.9976 accounts for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2022

For FY 2021, we established a capital Federal rate of $466.21 (85 FR 59048, as corrected in 85 FR 78756). We are proposing to establish an update of 0.70 percent in determining the FY 2022 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $471.89 for FY 2022. The proposed national capital Federal rate for FY 2022 was calculated as follows:

- The proposed FY 2022 update factor is 1.007; that is, the proposed update is 0.7 percent.
- The proposed FY 2022 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 1.0001.
- The proposed FY 2022 lowest quartile hospital wage index budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index is 0.9976.
- The proposed FY 2022 outlier adjustment factor is 0.9467.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2022 affects the computation of the proposed FY 2022 national capital Federal rate in comparison to the FY 2021 national capital Federal rate. The proposed FY 2022 update factor has the effect of increasing the capital Federal rate by 0.70 percent compared to the FY 2021 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.01 percent. The proposed FY 2022 lowest quartile hospital wage index budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 0.49 percent compared to the FY 2021 capital Federal rate. The proposed FY 2022 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.01 percent compared to the FY 2021 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 1.22 percent, compared to the FY 2021 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2021 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2022 CAPITAL FEDERAL RATE

	FY 2021	FY 2022	Change	Percent Change
Update Factor[1]	1.0110	1.0070	1.0070	0.70
GAF/DRG Adjustment Factor[1]	1.0008	1.0001	1.0001	0.01
Lowest Quartile Adjustment Factor[2]	0.9927	0.9976	1.0049	0.49
Outlier Adjustment Factor[3]	0.9466	0.9467	1.0001	0.01
Capital Federal Rate	$466.21	$471.89	1.0122	1.22[4]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2021 to FY 2022 resulting from the application of the proposed 1.0001 GAF/DRG budget neutrality adjustment factor for FY 2022 is a net change of 0.0001 (or 0.01 percent).

[2] The FY 2021 lowest quartile adjustment factor accounts for the cumulative effect of the budget neutrality factors applied in FYs 2020 and 2021 for the lowest quartile hospital wage index adjustment and the 5 percent cap on wage index decreases. The value was determined as the product of the FY 2020 budget neutrality factor of 0.9964 (84 FR 42639) and the FY 2021 budget neutrality factor of 0.9963 (85 FR 59047). We are proposing that this adjustment factor would not be built permanently into the capital Federal rate; that is, the factor would not be applied cumulatively in determining the capital Federal rate. Therefore, we calculate the net change resulting from the application of the proposed FY 2022 lowest quartile adjustment factor is 0.9976/0.9927 or 1.0049 (or 0.49 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2022 outlier adjustment factor is 0.9467/0.9466 or 1.0001 (or 0.01 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2022

For purposes of calculating payments for each discharge during FY 2022, the capital Federal rate is adjusted as follows: (Standard Federal Rate) x (DRG weight) x (GAF) x (COLA for hospitals located in Alaska and Hawaii) x (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier threshold for FY 2022 is in section II.A. of this Addendum. For FY 2022, a case will qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.j. of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $30,967.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2022 IPPS/LTCH PPS proposed rule, we are proposing to rebase and revise the IPPS operating and capital market baskets to reflect a 2018 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of this proposed rule.

2. Forecast of the CIPI for FY 2022

Based on IHS Global Inc.'s fourth quarter 2020 forecast, for this proposed rule, we are forecasting the proposed 2018-based CIPI to increase 1.0 percent in FY 2022. This reflects a projected 1.7 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.0 percent increase in other capital expense prices in FY 2022, partially offset by a projected 3.7 percent decline in vintage-weighted interest expense prices in FY 2022. The weighted average of these three factors produces the forecasted 1.0 percent increase for the proposed 2018-based CIPI in FY 2022. We are also proposing that if more recent data becomes available (for example, a more recent estimate of the increase in the 2018-based CIPI), we would use such data, if appropriate, to determine the FY 2022 increase in the 2018-based CIPI for the final rule.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2022

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of increase limits established under § 413.40 of the regulations.)

We are proposing to rebase and revise the IPPS operating basket to a 2018 base year. Therefore, we are proposing to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2022 percentage increase in the proposed 2018-based IPPS operating market basket.

For this FY 2022 IPPS/LTCH PPS proposed rule, based on IGI's 2020 fourth quarter forecast, we estimate that the proposed 2018-based IPPS operating market basket update for FY 2022 would be 2.5 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2022 rate-of-increase percentage that would be applied to the FY 2021 target amounts in order to calculate the FY 2022 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals would be 2.5 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the FY 2022 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2022.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the proposed changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2022. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2022

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2022

1. Overview

In section VIII. of the preamble of this proposed rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2022.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VIII.C.2 of the preamble of this proposed rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2022 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2022 we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2022, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2022 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.5. of this Addendum to this proposed rule.

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.2 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.4 percent less the MFP adjustment of 0.2 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are proposing to apply a factor of 1.022 to the FY 2021 LTCH PPS standard Federal payment rate of $ 43,755.34 to determine the proposed FY 2022 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and § 412.523(c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2022 as required under the LTCH QRP. Therefore, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.2 percent (that is, an update factor of 1.002) for FY 2022 for LTCHs that fail to submit the required quality reporting data for FY 2022 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2022 LTCH PPS standard Federal payment rate of 1.002458, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $44,827.87 (calculated as $43,755.34 × 1.022 × 1.002458) for FY 2022. For LTCHs that fail to submit quality reporting data for FY 2022, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $43,950.62 (calculated as $43,755.34 × 1.002 × 1.002458) for FY 2022.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2022

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index

is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The proposed FY 2022 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2021, through September 30, 2022, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the Core Based Statistical Areas (CBSAs) established by OMB, which are based on the 2010 decennial census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013 in OMB Bulletin No. 13–01. (We note we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf.*

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017, OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018, OMB Bulletin No. 18–03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data. We adopted the updates set forth in OMB Bulletin No. 18–04 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59050 through 59051). A copy of the September 14, 2018, OMB Bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04, which was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area and one new component of an existing Combined Statistical Area.

After reviewing OMB Bulletin No. 20–01, we have determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the CBSA-based labor market area delineations used under the LTCH PPS. Specifically, all changes were to New England City and Town Area delineations (NECTA) and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The LTCH PPS CBSA-based labor market area delineations do not utilize NECTA definitions, and considers hospitals located in Micropolitan Statistical Areas in each State's rural area. Therefore, we are proposing to adopt the updates set forth in OMB Bulletin No. 20–01; however, specific wage index updates are not necessary as a result of the adopting the updates.

We believe the CBSA-based labor market area delineations as established in OMB Bulletin 20–01 will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, in this proposed rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to adopt the revisions announced in OMB Bulletin No. 20–01 to the CBSA-based labor market area delineations under the LTCH PPS, effective October 1, 2022. As already noted, our proposal to adopt the updates set forth in OMB Bulletin No. 20–01 will not alter the LTCH PPS area wage level adjustment because our CBSA-based labor market area delineations are the same as the CBSA-based labor market area delineations adopted in the FY 2021 IPPS/LTCH PPS final rule based on OMB Bulletin No. 18–04 (85 FR 59050 through 59051). We also note that, as discussed in section III.A.2. of the preamble of this proposed rule, we are also proposing to use these CBSA-based delineations under the IPPS.

We note that, in connection with our adoption in FY 2021 of the updates in OMB bulletin 18–04, for FY 2021 we adopted a policy to place a 5 percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index in FY 2020, so that an LTCH's wage index for FY 2021 would not be less than 95 percent of its wage index for FY 2020. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59052 through 59053) for a complete discussion of this transition. As finalized in the FY 2021 IPPS/LTCH PPS final rule, this transition expires at the end of FY 2021.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, for FY 2013 through FY 2016, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) For FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year. In addition, for FY 2017 through FY 2020, we determined

the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2013-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).) Then, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017 based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In this proposed rule, consistent with our historical practice, we are proposing to establish that the LTCH PPS labor-related share for FY 2022 is the sum of the FY 2022 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specifically, we are proposing to establish that the labor-related share for FY 2022 includes the sum of the labor-related portion of operating costs from the 2017-based LTCH market basket (that is, the sum of the FY 2022 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services) and a portion of the relative importance of Capital-Related cost weight from the 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2022. Based on IHS Global Inc.'s fourth quarter 2020 forecast of the 2017-based LTCH market basket, the sum of the FY 2022 relative importance for Wages and Salaries, Employee Benefits, Professional Fees: Labor-related, Administrative and Facilities Support Services, Installation Maintenance & Repair Services, and All Other: Labor-related Services is 63.7 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based and 2013-based LTCH market baskets). Since the FY 2022 relative importance for Capital-Related costs is 9.4 percent based on IHS Global Inc.'s fourth quarter 2020 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.4 percent to determine the labor-related share of capital-related for FY 2022 of 4.3 percent. Therefore, we are proposing to establish a total labor-related share for FY 2022 of 68.0 percent (the sum of 63.7 percent for the operating cost and 4.3 percent for the labor-related share of capital-related cost).

4. Proposed Wage Index for FY 2022 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 59051 through 59052), we calculated the FY 2021 LTCH PPS area wage index values using the same data used for the FY 2021 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2017), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2021 LTCH PPS area wage index values consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2022 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to employ our historical practice of using the same data we are proposing to use to compute the proposed FY 2022 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2018) because these data are the most recent complete data available.

In addition, we are proposing to compute the FY 2022 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We are also proposing to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2022 we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2018 IPPS wage data that we are proposing to use to determine the proposed FY 2022 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the proposed FY 2022 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/wageindex*.

Based on the FY 2018 IPPS wage data that we are proposing to use to determine the proposed FY 2022 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2022. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Proposed Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2022, in accordance with § 412.523(d)(4), we are proposing to apply an

area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773).

Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2022 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2021 wage index values and the FY 2021 labor-related share of 68.1 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2022 wage index values and the proposed FY 2022 labor-related share of 68.0 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum to this proposed rule and the labor-related share is discussed in section V.B.3. of this Addendum to this proposed rule.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2021 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2022 updates to the area wage level adjustment (calculated in Step 2) to determine the proposed budget neutrality factor for updates to the area wage level adjustment for FY 2022 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the proposed FY 2022 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2022 LTCH PPS standard Federal payment rate after the application of the proposed FY 2022 annual update.

We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the proposed FY 2022 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2022 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.002458. Accordingly, in section V.A. of the Addendum to this proposed rule, we applied the proposed area wage level adjustment budget neutrality factor of 1.002458 to determine the proposed FY 2022 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Proposed Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket); the first year of our current policy was FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482) for a detailed description of this methodology. For the FY 2014 IPPS/LTCH PPS final rule, we updated the COLA factors for Alaska and Hawaii published by OPM for 2009 using this methodology (78 FR 50997 through 50998). For the FY 2018 IPPS/LTCH PPS final rule, we again updated the COLA factors using this same methodology (82 FR 38539 through 38540) to correspond to the updated of the labor-related share of the IPPS market basket, which reflected 2014 cost shares. As discussed in this proposed rule, we continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii.

For FY 2022, we are proposing to update the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Specifically, we are proposing to update the 2009 OPM COLA factors by a comparison of the growth in the Consumer Price Indices (CPIs) for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We note that for the prior update to the COLA factors, we used the growth in the CPI for Anchorage and the CPI for Honolulu. Beginning in 2018, these indexes were renamed to the CPI for Urban Alaska and the CPI for Urban Hawaii, respectively, due to the BLS updating its sample to reflect the data from the 2010 decennial census on the distribution of the urban population (*https://www.bls.gov/regions/west/factsheet/2018cpirevisionwest.pdf*, accessed January 22, 2021). The CPI for Urban Alaska area covers Anchorage and Matanuska-Susitna Borough in the State of Alaska and the CPI for Urban Hawaii covers Honolulu in the State of Hawaii. BLS notes that the indexes are considered continuous over time, regardless of name or composition changes.

Because BLS publishes CPI data for only Urban Alaska and Urban Hawaii, using the methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively. We believe that the relative price differences between these urban areas and the United States (as measured by the CPIs mentioned previously) are appropriate proxies for the relative price differences between the other areas of Alaska and Hawaii and the United States.

BLS publishes the CPI for All Items for Urban Alaska, Urban Hawaii, and for the average U.S. city. However, consistent with our methodology finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The current composition of the CPI for All Items for all of the respective areas is approximately 40 percent commodities and 60 percent services. However, the IPPS nonlabor-related share for the proposed 2018-based IPPS market basket is comprised of a different mix of commodities and services. Therefore, we are proposing to create reweighted indexes for Urban Alaska, Urban Hawaii, and the average U.S. city using the respective CPI commodities index and CPI services index and using the approximate 57 percent commodities/43 percent services shares obtained from the proposed 2018-based IPPS market basket. We created reweighted indexes using BLS data for 2009 through 2020—the most recent data available at the time of this proposed rulemaking. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540) we created reweighted indexes based on the 2014-based IPPS market basket (which was adopted for the FY 2018 IPPS update) and BLS data for 2009 through 2016 (the most recent BLS data at the time of the FY 2018 IPPS/LTCH PPS rulemaking).

We continue to believe this methodology is appropriate because we continue to make a COLA for LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the LTCH PPS standard Federal payment rate by a COLA factor. We note that OPM's COLA factors were calculated with a statutorily mandated cap of 25 percent. As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540) under the COLA update methodology we finalized in the FY 2013 IPPS/LTCH PPS final rule, we exercised our discretionary authority to adjust payments to LTCHs in Alaska and Hawaii by incorporating this cap. In applying this finalized methodology for updating the COLA factors, for FY 2022, we are proposing to continue to use such a cap, as our policy is based on OPM's COLA factors (updated by the methodology described previously).

Applying this methodology, the COLA factors that we are proposing to establish for

FY 2022 to adjust the nonlabor-related portion of the LTCH PPS standard Federal rate for LTCHs located in Alaska and Hawaii are shown in this table. For comparison purposes, we also are showing the COLA factors for FYs 2018 through 2021.

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAI UNDER THE LTCH PPS FOR FY2022

Area	FY 2018 through FY 2021	Proposed FY 2022
Alaska:		
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.25	1.22
Rest of Alaska	1.25	1.24
Hawaii:		
City and County of Honolulu	1.25	1.25
County of Hawaii	1.21	1.22
County of Kauai	1.25	1.25
County of Maui and County of Kalawao	1.25	1.25

D. Proposed Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs, as previously noted, the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. Proposed LTCH Total CCR Ceiling

Ordinarily, for this FY 2022 proposed rule, we would use IPPS total CCR data from the December 2020 update of the Provider Specific File (PSF) for the purposes of calculating the proposed LTCH total CCR ceiling for FY 2022. However, for many IPPS hospitals, these IPPS total CCR data were derived from cost reports that ended during the COVID–19 PHE. As discussed in section VIII.A.4. of the preamble of this proposed rule, we believe the utilization patterns reflected in these cost reports were significantly impacted by the COVID–19 PHE. Since the IPPS total CCR data from the March 2020 update of the PSF was derived from cost reports ending prior to the COVID–19 PHE, we believe for the reasons discussed

in section VIII.A.4. of the preamble of this proposed rule that these are the best available data at this time for the purposes of calculating the proposed LTCH total CCR ceiling for FY 2022. Therefore, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling but using the IPPS total CCR data from the March 2020 update of the PSF, we are proposing to establish an LTCH total CCR ceiling of 1.24 under the LTCH PPS for FY 2022 in accordance with § 412.525(a)(4)(iv)(C)(2) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we are proposing to use the best available data, if applicable, to determine the LTCH total CCR ceiling for FY 2022 in the final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

c. Proposed LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Ordinarily, for this proposed rule, we would use IPPS total CCR data from the December 2020 update of the PSF for the purposes of determining the LTCH statewide average CCRs for FY 2022. However, for many IPPS hospitals, these IPPS total CCR data were derived from cost reports that ended during the COVID–19 PHE. As discussed in section VIII.A.4 of the preamble of this proposed rule, we believe the utilization patterns reflected in these cost reports were significantly impacted by the COVID–19 PHE. Since the IPPS total CCR data from the March 2020 update of the PSF was derived from cost reports ending prior to the COVID–19 PHE, for the reasons discussed in section VIII.A.4. of the preamble of this proposed rule, we believe that these are the best available data at this time for the purposes of determining the LTCH statewide average CCRs for FY 2022. Therefore, in this proposed rule, using our established methodology for determining the LTCH statewide average CCRs, but based on IPPS ''total CCR'' data from the March 2020 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2021, through September 30, 2022, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing to use the best available data, if applicable, to determine the LTCH PPS statewide average total CCRs for FY 2022 in the final rule.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there were no short-term, acute care IPPS hospitals classified as rural or LTCHs located in these rural areas as of March 2020. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 0.949. Because this is much higher than the statewide urban average (0.459) and furthermore implies costs are nearly equal to charges, as with Connecticut, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Massachusetts in Table 8C. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In this proposed rule, we are proposing to adjust our methodology for calculating the

applicable fixed-loss amount for FY 2022 for LTCH PPS standard Federal payment rate cases, while maintaining estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We specifically are proposing to make a technical change to the methodology for determining the charge inflation factor that we apply to the charges on the MedPAR claims when calculating the proposed fixed-loss amount for FY 2022. We also are proposing to make a technical change to the methodology for determining the CCRs to use when calculating the proposed fixed-loss amount for FY 2022. Furthermore, we are proposing that these proposed technical changes to the methodology for determining the charge inflation factor and the CCRs we use when calculating the fixed-loss amount would become a permanent part of our methodology for subsequent years as well. These proposed technical changes are described in greater detail in sections V.D.3.b.(1). and V.D.3.b.(2). of the Addendum to this proposed rule.

(1) Proposed Charge Inflation Factor for Use in Determining the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor. Historically, as explained in in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59056), when determining the fixed-loss amount, charges were inflated with a growth factor calculated from quarterly market basket update values (determined by the Office of the Actuary). However, an analysis of the annual increase in actual charges (or charge inflation) calculated from the historical MedPAR claims compared with previous estimates using the quarterly market basket update values showed the actual charge inflation has been generally higher than the estimate. For example, when we set rates for FY 2019, we used a 2-year charge inflation factor of 5.7 percent based on the quarterly market basket update values. This factor was applied to charges from the FY 2017 MedPAR claims in order to inflate them to projected FY 2019 levels. However, our analysis of the actual FY 2019 MedPAR claims data shows that the actual growth in charges that occurred from FY 2017 to FY 2019 for standard Federal payment rate cases was 15.2 percent.

For greater accuracy in calculating the fixed-loss amount, we are proposing to make a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.h.(2) of the Addendum to this proposed rule), we are proposing to determine the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR claims data, instead of using estimates calculated from quarterly market basket update values. In this proposed rule, we describe the general methodology we are proposing to use to calculate the charge inflation factor for FY 2022 and subsequent years. We discuss in greater detail later in this section our specific application of this proposal for FY 2022, including the specific data we propose to use for FY 2022 after considering the impact the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 LTCH data.

Step 1—Identify LTCH PPS standard Federal payment rate cases.

The first step in our proposed methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove statistical outliers.

The next step in our proposed methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. We then remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the charge inflation factor.

The final step in our proposed methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. We then calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

As discussed in section VIII.A.4. of the preamble of this proposed rule, we are proposing to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE. For the purposes of calculating the proposed charge inflation factor for FY 2022, we are proposing to use the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our proposed methodology. As discussed in greater detail in section VIII.A.4. of the preamble of this proposed rule, due to the significant impact that the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 MedPAR claims, we believe these are the best available data at this time for the purposes of calculating the proposed charge inflation factor for FY 2022.

Therefore, for this proposed rule, we trimmed the March 2020 update of the FY 2019 MedPAR file and the March 2019 update of the FY 2018 MedPAR file using our proposed methodology. To compute the 1-year average annual rate-of-change in charges per case for FY 2022, we compared the average covered charge per case of $195,362 ($13,926,931,065/71,288 cases) from FY 2018 to the average covered charge per case of $207,224 ($14,172,496,534/68,392 cases) from FY 2019. This rate-of-change was 6.0723 percent and results in a proposed 1-year charge inflation factor of 1.060723, a proposed 2-year charge inflation factor of 1.125133 (calculated by squaring the proposed 1-year factor), and a proposed 3-year charge inflation factor of 1.193455 (calculated by cubing the proposed 1-year factor). We propose to inflate the billed charges obtained from the FY 2019 MedPAR file by this 3-year charge inflation factor of 1.193455 when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022.

(2) Proposed CCRs for Use in Determining the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

Historically, as explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59055 through 59056), when determining the fixed-loss amount, we used CCRs from the most recently available PSF file without any adjustment. By not making any adjustment, we assumed that CCRs in the current year would, on average, stay at the same level in the upcoming year. However, after examining actual changes to LTCH CCRs over time, we no longer believe this to be an appropriate assumption to make, as in general LTCH CCRs have not stayed at the same level year-to-year. For example, when we set rates for FY 2019, we assumed that CCRs would stay at the same level as the CCRs obtained from the March 2018 PSF. However, our calculations show that on average, CCRs declined 3.8 percent from March 2018 to March 2019.

For greater accuracy in calculating the fixed-loss amount, we are proposing to adjust the methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.h.(2). of the Addendum to this proposed rule), we are proposing to adjust CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case weighted CCR for LTCHs. We believe these adjusted CCRs will more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs. In this section, we describe the general methodology we are proposing to use to calculate the CCR adjustment factor for FY 2022 and subsequent years. We discuss in greater detail later in this section our specific application of this proposal for FY 2022,

including the specific data we propose to use after considering the impact the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 LTCH data.

Step 1—Assign providers their historical CCRs.

The first step in our proposed methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available one year prior to the most recently available PSF.

Step 2—Trim providers with insufficient CCR data.

The next step in our proposed methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove statistical outliers.

The next step in our proposed methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate the CCR adjustment factor.

The final step in our proposed methodology is to calculate, across all remaining providers after application of Step 3, the average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short-stay-outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

In this proposed rule, we are proposing to use the FY 2019 data for the FY 2022 LTCH PPS ratesetting in situations where the utilization patterns reflected in the FY 2020 data were significantly impacted by the COVID–19 PHE, for the reasons discussed in section VIII.A.4. of the preamble of this proposed rule. Ordinarily, for this FY 2022 proposed rule, we would use CCR data from the December 2020 update of the PSF when determining the CCRs used for calculating the proposed fixed-loss amount for FY 2022. However, for many LTCHs, these CCR data were derived from cost reports that ended during the COVID–19 PHE. As also discussed in section VIII.A.4. of the preamble of this proposed rule, we believe the utilization patterns reflected in these cost reports were significantly impacted by the COVID–19 PHE. Therefore, for the purposes of determining the CCRs used for calculating the proposed fixed-loss amount for FY 2022, we are proposing to use the March 2020 PSF as the most recently available PSF and the March 2019 PSF as the PSF that was made available one year prior to the most recently available PSF, as described in our proposed methodology. Since the CCR data from the March 2020 update of the PSF was derived from cost reports ending prior to the COVID–19 PHE, as discussed in section VIII.A.4. of the preamble of this proposed rule, we believe these are the best available data at this time for the purposes of determining the CCRs used to calculate the proposed fixed-loss amount for FY 2022. In addition, we also are proposing to use claims from the March 2020 update of the FY 2019 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our proposed methodology. As discussed in greater detail in section VIII.A.4. of the preamble of this proposed rule, due to the significant impact that the COVID–19 PHE had on the utilization patterns reflected in the FY 2020 MedPAR claims, we believe these are the best available data at this time for the purposes of calculating the average case-weighted CCRs.

Specifically, to calculate the CCRs we proposed to use in this proposed rule, we followed the proposed methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the March 2020 update of the FY 2019 MedPAR file, we identified their CCRs from both the March 2019 PSF and March 2020 PSF. After performing the trims outlined in our proposed methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2019 MedPAR file (classified using Version 39 of the GROUPER) to calculate the case-weighted average CCRs. For this proposed rule, we calculated a proposed March 2019 national average case-weighted CCR of 0.256374 and a proposed March 2020 national average case-weighted CCR of 0.246517. We then calculated the proposed national CCR adjustment factor by dividing the March 2020 national average case-weighted CCR by the March 2019 national average case-weighted CCR. This results in a proposed 1-year national CCR adjustment factor of 0.961555 and a proposed 2-year national CCR adjustment factor of 0.924588 (calculated by squaring the proposed 1-year factor). When calculating the proposed fixed-loss amount for FY 2022, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the March 2020 PSF or whose CCR was missing in the March 2020 PSF. For all other providers, we multiplied their CCR from the March 2020 PSF by the proposed 2-year national CCR adjustment factor.

(3) Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2022

In this proposed rule, we are proposing no other changes to our methodology for calculating the proposed applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases. Therefore, for FY 2022, using the best available data, we calculated a proposed fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the proposed rule). As described earlier in this section and discussed in more detail in section VIII.A.4. of the preamble of this proposed rule, we believe the FY 2020 MedPAR claims were significantly impacted by COVID–19 PHE. As a result, we are proposing to use LTCH claims data from the March 2020 update of the FY 2019 MedPAR file to calculate a proposed fixed-loss amount for FY 2022. Therefore, based on LTCH claims data from the March 2020 update of the FY 2019 MedPAR file adjusted for charge inflation and adjusted CCRs from the March 2020 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022 of $32,680 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2022 payments for such cases. We also are proposing to continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $32,680).

Consistent with our historical practice, we are proposing to use the best available LTCH claims data and CCR data, if applicable, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2022 in the final rule.

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the

Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2021, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2018 and FY 2019 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2021, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2021 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2021. In particular, in FY 2021, we established the fixed-loss amount for site neutral payment rate cases as the FY 2021 IPPS fixed-loss amount of $29,064 (as corrected at 85 FR 78756).

As noted earlier, because not all claims in the data used for this FY 2022 IPPS/LTCH PPS proposed rule were subject to the unblended site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2021 when developing a fixed-loss amount for site neutral payment rate cases for FY 2022. Our actuaries continue to project that site neutral payment rate cases in FY 2022 will continue to mirror an IPPS case paid under the same MS–DRG. That is, our actuaries continue to project that the costs and resource use for FY 2022 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the FY 2019 LTCH claims data used in the development of this FY 2022 IPPS/LTCH PPS proposed rule, approximately 75 percent of LTCH cases were paid the LTCH PPS standard Federal payment rate and approximately 25 percent of LTCH cases were paid the site neutral payment rate for discharges occurring in FY 2019.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2022 is the IPPS fixed-loss amount for FY 2022. Therefore, consistent with past practice, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the proposed IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $30,967, which is the same proposed FY 2022 IPPS fixed-loss amount discussed in section II.A.4.j.(1). of the Addendum to this proposed rule. Accordingly, for FY 2022, we are proposing to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $30,967).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2022 would not result in any increase in estimated aggregate FY 2022 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2022, in general, we are proposing to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2022 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2022 would not result in any increase in estimated aggregate FY 2022 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2022. In order to achieve this, for FY 2022, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0–5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time

period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2022, as discussed in greater detail in section V.E.4.b. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 72.14 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2022. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 54.11 percent (the product of 75 percent and 72.14 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2022, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 79.11 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 54.11 percent = 79.11 percent).

Therefore, for FY 2022, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 79.11 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that, if more recent data became available, we would use that data to determine this factor in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2022

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2022 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this proposed and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2022 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2022 of $44,827.87, as discussed in section V.A. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2022 in the following example:

Example:

During FY 2022, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a proposed FY 2022 LTCH PPS wage index value of 1.0392 (obtained from Table 12A listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2022 of 0.9448 (obtained from Table 11 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). The LTCH submitted quality reporting data for FY 2022 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient case in FY 2022, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2022 LTCH PPS standard Federal payment rate ($44,827.87) by the proposed labor-related share (0.68 percent) and the proposed wage index value (1.0392). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (0.32 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9448) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2022 ($43,482.34). The table illustrates the components of the calculations in this example.

Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate	$44,827.87
Proposed Labor-Related Share	x 0.68
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $30,482.95
Proposed Wage Index (CBSA 16984)	x 1.0392
Proposed Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $31,677.88
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($44,827.87 x 0.32)	+ $14,344.92
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $46,022.80
Proposed MS-LTC-DRG 189 Relative Weight	x 0.9448
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $43,482.34

VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2021, for the FY 2022 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed in the proposed rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59059 through 59060).

In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital-level data for the FY 2022 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As was the case for the FY 2021 IPPS/LTCH PPS proposed and final rules, we are no longer including Table 15, which had typically included the fiscal year readmissions payment adjustment factors because hospitals have not yet had the opportunity to review and correct the data before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2022, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2022 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2021. We expect Table 15 will be posted on the CMS website in the fall of 2021.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this proposed rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed rule are generally available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2022 IPPS Proposed rule Home Page'' or ''Acute Inpatient -Files-for Download.'' We refer readers to section I.O. of the Appendix A of this proposed rule for a discussion of the supplemental data files based on the use of the FY 2020 data that we would ordinarily use for FY 2022 ratesetting, which we are also making available on the CMS website.

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2022 Proposed Rule

Table 3.—Proposed Wage Index Table by CBSA—FY 2022 Proposed Rule

Table 4A.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2022 Proposed Rule

Table 4B.—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2022 Proposed Rule

Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2022

Table 6A.—New Diagnosis Codes—FY 2022

Table 6B.—New Procedure Codes—FY 2022

Table 6C.—Invalid Diagnosis Codes—FY 2022

Table 6D.—Invalid Procedure Codes—FY 2022

Table 6E.—Revised Diagnosis Code Titles—FY 2022

Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List-FY 2022

Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2022

Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2022

Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2022

Table 6I.1.—Proposed Additions to the MCC List—FY 2022

Table 6I.2.—Proposed Deletions to the MCC List—FY 2022

Table 6J.1.—Proposed Additions to the CC List—FY 2022

Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes—FY 2022 (Table 6P contains multiple tables, 6P.1a. through 6P.3a that include the ICD–10–CM and ICD–10–PCS code lists relating to specific proposed MS–DRG changes. These tables are referred to throughout section II.D. of the preamble of this proposed rule.)

Table 7A.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update March 2020—GROUPER Version 38 MS–DRGs

Table 7B.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update March 2020—GROUPER Version 39 MS–DRGs

Table 8A.—Proposed FY 2022 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2022 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 16.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors That Would Apply for FY 2022 If Our Proposals to Revise the Scoring and Payment Methodology For That Program Year Are Not Finalized

Table 18.—Proposed FY 2022 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2022 proposed rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1752–P:

Table 8C.—Proposed FY 2022 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2021 through September 30, 2022

Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2021 through September 30, 2022

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2021 through September 30, 2022

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TABLE 1A.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2022

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.3 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.425 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.675 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.2 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,150.84	$1,989.45	$4,074.76	$1,952.99	$4,125.48	$1,977.30	$4,049.40	$1,940.83

TABLE 1B.— PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2022

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.3 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.425 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.675 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.2 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,806.98	$2,333.31	$3,737.21	$2,290.54	$3,783.72	$2,319.06	$3,713.94	$2,276.29

TABLE 1C.— PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2022

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 2.3)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 1.675)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,806.98	$2,333.31	$3,783.72	$2,319.06

[1] For FY 2022, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.— PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2022

	Rate
National	471.89

TABLE 1E.— LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2022

	Full Update (2.2 Percent)	Reduced Update* (0.2 Percent)
Standard Federal Rate	$44,827.87	$43,950.62

* For LTCHs that fail to submit quality reporting data for FY 2022 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

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Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, and the proposals and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

We estimate that the proposed changes for FY 2022 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals, and therefore, estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $2.5 billion increase in FY 2022 payments, primarily driven by: (a) A combined $2.2 billion increase in FY 2022 operating payments, including uncompensated care payments, and (b) a combined increase of $0.3 billion resulting from estimated changes in new technology add-on payments, the recently enacted statutory provision that provides for an imputed floor adjustment for all-urban states in a non-budget neutral manner beginning in FY 2022 and discussed in section III.G.2. of this rule, and FY 2022 capital payments. These proposed changes are relative to payments made in FY 2021. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments by approximately $52 million in FY 2022 relative to FY 2021.

Our operating impact estimate includes the proposed 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this proposed rule. In addition, our operating payment impact estimate includes the proposed 2.3 percent hospital update to the standardized amount (which includes the estimated 2.5 percent market basket update reduced by the proposed 0.2 percentage point for the multifactor productivity (MFP) adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on

some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2022, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those proposed policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related- costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 27 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As discussed in section II.A.4 of the Addendum to this proposed rule, consistent with our proposed use of the Provider Specific File (PSF), we included 3,198 IPPS acute care hospitals in our analysis. This represents approximately 54 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,417 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of proposed changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2022 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As discussed in section II.A.4 of the Addendum to this proposed rule, consistent with our proposed use of the PSF, there were 95 children's hospitals, 11 cancer hospitals, 6 short term- acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 15 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the proposed rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. of this Appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2022 percentage increase in the proposed 2018-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's 2020 fourth quarter forecast of the proposed 2018-based IPPS market basket increase, we are estimating the proposed FY 2022 update to be 2.5 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section IV.A. of the preamble of this proposed rule. We are proposing that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2022. However, the Affordable Care Act requires an adjustment for multifactor productivity (proposed 0.2 percentage point reduction for FY 2022), resulting in a proposed 2.3 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.A. of the preamble of this proposed rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the proposed update is the percentage increase in the proposed 2018-based IPPS operating market basket for FY 2022, estimated at 2.5 percent.

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2022 for operating costs of acute care hospitals. The proposed FY 2022 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall proposed percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2022 operating payments would increase by 2.7 percent, compared to FY 2021. In addition to the proposed applicable percentage increase, this amount reflects the proposed +0.5 percentage point permanent

adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. As discussed in Section I.A of this proposed rule, we believe that the FY 2019 claims data is the best available data for purposes of the proposed FY 2022 ratesetting and this impact analysis reflects the use of that data. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2019 MedPAR file and are consistent with our proposed use of Provider-Specific File (PSF) data, as discussed previously in this proposed rule. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals, specifically, cost report data from the FY 2018 HCRIS, as also discussed previously in this proposed rule. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2019 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of proposed payments under the capital IPPS, and the impact of proposed payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2022 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the application of the proposed applicable percentage increase of 2.3 percent (that is, a 2.5 percent market basket update with a proposed reduction of 0.2 percentage point for the multifactor productivity adjustment), and a proposed 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the proposed applicable percentage increase (including the market basket update and the proposed multifactor productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2018, compared to the FY 2017 wage data, to calculate the proposed FY 2022 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that will be effective for FY 2022.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2022. This provision is not budget neutral.
- The total estimated change in payments based on the proposed FY 2022 policies relative to payments based on FY 2021 policies.

To illustrate the impact of the proposed FY 2022 changes, our analysis begins with a FY 2021 baseline simulation model using: The FY 2021 applicable percentage increase of 2.4 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2021 MS–DRG GROUPER (Version 38); the FY 2021 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2021 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, we are proposing that, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.675 percent. At the time this impact was prepared, 65 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2022 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2022 using a reduced update for these hospitals.

For FY 2022, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.425 percent. At the time this impact analysis was prepared, 105 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2022 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2022 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.2 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 24 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2022 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2022 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the proposed percent change in payments per case from FY 2021 to FY 2022. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2022 using a proposed applicable percentage increase of 2.3 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.5 percent with a

proposed 0.2 percentage point reduction for the multifactor productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 1.675 percent. This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a proposed update of 0.425 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a proposed update of −0.2 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 2.3 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2021 to FY 2022 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2021 that are no longer reclassified in FY 2022. Conversely, payments may increase for hospitals not reclassified in FY 2021 that are reclassified in FY 2022.

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2022. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,198 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: Urban and rural. There are 2,459 hospitals located in urban areas and 739 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2022 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 1,965, and 1,233, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,034 nonteaching hospitals in our analysis, 907 teaching hospitals with fewer than 100 residents, and 257 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, MDHs and RRCs). There were 555 RRCs, 304 SCHs, 148 MDHs, 151 hospitals that are both SCHs and RRCs, and 24 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total inpatient days. These data were taken from the FY 2018 or FY 2017 Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2022 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2022

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2022 Changes (7)[8]
All Hospitals	3,198	2.8	0.0	0.0	0.0	0.0	0.1	2.7
By Geographic Location:								
Urban hospitals	2,459	2.8	0.0	0.0	-0.1	0.0	0.1	2.7
Rural hospitals	739	2.5	0.1	0.2	1.1	-0.2	0.1	2.9
Bed Size (Urban):								
0-99 beds	633	2.7	0.0	0.0	-0.6	0.1	0.3	2.8
100-199 beds	755	2.8	0.0	0.0	-0.2	0.2	0.1	2.7
200-299 beds	427	2.8	0.0	0.1	0.2	0.1	0.1	2.6
300-499 beds	421	2.8	0.0	0.0	0.0	0.0	0.2	2.7
500 or more beds	223	2.7	0.0	-0.1	-0.2	-0.1	0.0	2.7
Bed Size (Rural):								
0-49 beds	313	2.4	0.1	0.3	0.3	-0.1	0.2	4.0
50-99 beds	254	2.5	0.1	0.2	0.8	-0.1	0.2	2.6
100-149 beds	94	2.5	0.1	0.3	1.0	-0.2	0.0	2.6
150-199 beds	39	2.6	0.0	0.1	1.3	-0.2	0.1	2.7
200 or more beds	39	2.6	0.1	0.1	2.0	-0.2	0.0	3.0
Urban by Region:								
New England	112	2.8	0.0	-1.0	1.8	2.7	0.0	2.2
Middle Atlantic	304	2.8	0.0	-0.3	0.1	-0.3	0.1	2.0
East North Central	381	2.8	0.0	-0.1	-0.2	-0.3	0.0	2.8
West North Central	160	2.7	-0.1	0.3	-0.7	-0.3	0.7	3.1
South Atlantic	402	2.8	0.0	0.3	-0.5	-0.3	0.0	3.1
East South Central	144	2.8	0.0	-0.1	-0.3	-0.3	0.0	2.7
West South Central	364	2.8	0.0	-0.4	-0.5	-0.3	0.0	2.6
Mountain	172	2.7	0.0	0.0	0.0	0.0	0.2	2.6
Pacific	370	2.7	-0.1	0.5	0.2	0.4	0.1	2.9
Puerto Rico	50	2.8	-0.4	-0.2	-1.0	0.2	0.1	2.0
Rural by Region:								
New England	19	2.6	0.0	-0.4	1.4	-0.2	0.0	3.5
Middle Atlantic	50	2.5	0.2	0.3	0.7	-0.2	0.0	2.6
East North Central	114	2.5	0.1	0.2	0.8	-0.1	0.0	2.5
West North Central	89	2.3	0.0	0.0	0.3	-0.1	0.2	2.8
South Atlantic	114	2.5	0.1	1.0	1.3	-0.2	0.0	3.2
East South Central	144	2.7	0.1	-0.1	2.1	-0.2	0.1	2.9
West South Central	136	2.5	0.1	0.0	1.5	-0.3	0.0	2.6
Mountain	49	2.2	0.0	0.6	0.0	0.0	0.8	1.6
Pacific	24	2.4	0.0	0.0	1.1	-0.1	0.0	5.5
By Payment Classification:								
Urban hospitals	1,965	2.8	0.0	0.0	-0.5	0.0	0.1	2.6
Rural areas	1,233	2.7	0.0	-0.1	0.8	0.0	0.1	2.8
Teaching Status:								
Nonteaching	2,034	2.7	0.0	0.2	0.1	0.1	0.1	2.8

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2022 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2022 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2022 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2022 Changes (7)[8]
Fewer than 100 residents	907	2.8	0.0	0.0	0.0	0.0	0.2	2.6
100 or more residents	257	2.7	0.0	-0.1	-0.1	0.0	0.0	2.7
Urban DSH:								
Non-DSH	505	2.8	0.0	0.0	-0.5	0.0	0.2	2.6
100 or more beds	1,210	2.8	0.0	0.0	-0.5	0.0	0.1	2.7
Less than 100 beds	350	2.8	0.0	0.0	-0.5	0.3	0.2	2.9
Rural DSH:								
SCH	260	2.3	0.1	0.1	-0.2	0.0	0.1	2.7
RRC	622	2.7	0.0	-0.1	0.9	-0.1	0.1	2.7
100 or more beds	34	2.7	0.0	0.0	-0.5	1.5	0.0	2.5
Less than 100 beds	217	2.6	0.1	0.3	0.9	-0.3	0.2	3.3
Urban teaching and DSH:								
Both teaching and DSH	674	2.8	0.0	0.0	-0.6	-0.1	0.1	2.6
Teaching and no DSH	74	2.8	0.0	-0.1	-0.9	-0.2	0.1	2.0
No teaching and DSH	886	2.8	0.0	0.2	-0.4	0.2	0.1	2.8
No teaching and no DSH	331	2.8	0.0	0.1	-0.6	-0.2	0.2	2.7
Special Hospital Types:								
RRC	555	2.8	0.0	-0.1	0.9	-0.1	0.1	2.8
SCH	304	2.3	0.0	0.1	-0.1	0.0	0.0	2.7
MDH	148	2.5	0.1	0.0	0.4	-0.1	0.1	2.8
SCH and RRC	151	2.4	0.0	0.1	0.4	0.1	0.0	2.5
MDH and RRC	24	2.4	0.0	0.0	0.4	-0.1	0.0	2.3
Type of Ownership:								
Voluntary	1,883	2.8	0.0	-0.1	0.1	0.0	0.1	2.6
Proprietary	828	2.8	0.0	0.1	0.0	0.0	0.1	2.8
Government	487	2.7	0.0	0.2	-0.3	0.0	0.0	2.9
Medicare Utilization as a Percent of Inpatient Days:								
0-25	643	2.8	0.0	0.0	-0.5	-0.1	0.0	2.8
25-50	2,113	2.8	0.0	0.0	0.1	0.0	0.1	2.7
50-65	366	2.7	0.0	-0.1	0.1	0.4	0.2	2.0
Over 65	51	2.6	0.1	0.1	-0.9	-0.2	0.1	3.3
FY 2022 Reclassifications:								
All Reclassified Hospitals	1,048	2.7	0.0	-0.1	1.0	0.0	0.1	2.7
Non-Reclassified Hospitals	2,150	2.8	0.0	0.1	-0.9	0.0	0.1	2.7
Urban Hospitals Reclassified	860	2.8	0.0	-0.1	0.9	0.0	0.1	2.6
Urban Non-Reclassified Hospitals	1,612	2.8	0.0	0.1	-1.0	0.0	0.1	2.7
Rural Hospitals Reclassified Full Year	304	2.5	0.1	0.2	1.9	-0.2	0.0	2.7
Rural Non-Reclassified Hospitals Full Year	422	2.5	0.1	0.2	-0.3	-0.1	0.2	3.3
All Section 401 Reclassified Hospitals	550	2.7	0.0	-0.1	0.7	0.0	0.1	2.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.6	0.1	0.0	2.6	-0.2	0.0	3.1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2019, and hospital cost report data are from reporting periods beginning in FY 2018 and FY 2017.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.3 percent update to the national standardized amount and the proposed hospital-specific rate (the estimated 2.5 percent market basket update reduced by 0.2 percentage point for the proposed multifactor productivity adjustment), and the proposed 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the proposed changes to the Version 39 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data as the best available data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 1.000098 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2018 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.000277.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2022 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2022. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.987018.

[6] This column displays the effects of the proposed rural floor The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.993988.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2021 to FY 2022.

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a. Effects of the Proposed Hospital Update and Other Proposed Adjustments (Column 1)

As discussed in section IV.A. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 2.5 percent market basket update reduced by the proposed 0.2 percentage point for the multifactor productivity adjustment. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the FY 2022 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we are proposing to make a 2.8

percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 2.5 percent market basket update reduced by the proposed 0.2 percentage point for the multifactor productivity adjustment. As a result, we are proposing to make a 2.3 percent update to the hospital-specific rates.

Overall, hospitals would experience a 2.8 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate would experience a 2.3 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increase in payments.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2022 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2022, we are proposing to calculate the MS–DRGs using the FY 2019 MedPAR data grouped to the proposed Version 39 (FY 2022) MS–DRGs. The methodology to calculate the proposed relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 1.000098 to the standardized amount.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of the proposed updated wage data using FY 2018 cost report data, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2022 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01, 17–01, and 18–04. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index, to the FY 2020 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2020 wage index, and to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 18–04 for the FY 2021 wage index.)

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2022 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2017 and before October 1, 2018. The estimated impact of the updated wage data using the FY 2018 cost report data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other proposed payment parameters constant in this simulation. That is, Column 3 shows the proposed percentage change in payments when going from a model using the FY 2021 wage index, based on FY 2017 wage data, the labor-related share of 68.3 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2022 pre-reclassification wage index based on FY 2018 wage data with the proposed labor-related share of 67.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the proposed Version 39 MS–DRG GROUPER constant. The FY 2022 occupational mix adjustment is based on the CY 2019 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2022, we are proposing to calculate the proposed wage budget neutrality factor to ensure that payments under updated wage data and the proposed labor-related share of 67.6 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2022 wage budget neutrality factor is 1.000277 and the overall proposed payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2018 cost reports. Overall, the new wage data and the proposed labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 2.5 percent compared to FY 2021. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the proposed 2.5 percent increase in the national average hourly wage. Of the 3,140 hospitals with wage data for both FYs 2021 and 2022, 1,628 or 52 percent would experience an average hourly wage increase of 2.5 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2022 relative to FY 2021. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the internet on the CMS website) is used to adjust the labor-related share of a hospital's standardized amount, either 67.6 percent (as proposed) or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller proposed change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2022 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	10	0
Increase greater than or equal to 5 percent and less than 10 percent	32	49
Increase or decrease less than 5 percent	2,315	667
Decrease greater than or equal to 5 percent and less than 10 percent	50	2
Decrease 10 percent or more	4	0
Unchanged	11	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The proposed changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2022.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials by the MGCRB of reclassification requests to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this proposed rule.)

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.987018 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule). As noted elsewhere in this proposed rule, concurrent with this proposed rule, CMS has made publicly available the interim final rule with comment period titled ''Medicare Program; Modification of Limitations on Redesignation by the Medicare Geographic Classification Review Board (MGCRB)'' (CMS–1762–IFC). Also as noted elsewhere in this proposed rule, if certain hospitals receive higher wage indexes as a result of settlement or other resolution of pending litigation, we intend to include any amounts they receive by reason of those higher wage indexes in the calculation of the budget neutrality factor. If these hospitals do receive a higher wage index at the time of the final rule than they might otherwise have received, we estimate the FY 2022 budget neutrality adjustment could increase by as much as approximately one-half of a percentage point compared to the budget neutrality adjustment that might otherwise have been calculated.

Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.1 percent. By region, most rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website reflects the reclassifications for FY 2022.

e. Effects of the Proposed Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2021 IPPS/LTCH PPS final rules, and this FY 2022 IPPS/LTCH PPS proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same State. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the proposed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a proposed FY 2022 rural floor budget neutrality factor to be applied to the wage index of 0.993988, which would reduce wage indexes by 0.6 percent.

Column 5 shows the projected impact of the proposed rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2022 wage index of providers before the rural floor adjustment and the proposed post-reclassification FY 2022 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals that do not receive an increase to their wage index from the rural floor adjustment (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied to the wage index nationally. (As finalized in the FY 2020 IPPS/LTCH PPS final rule, we calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103.)

We estimate that 287 hospitals would receive the rural floor in FY 2022. All IPPS hospitals in our model would have their wage indexes reduced by the proposed rural floor budget neutrality adjustment of 0.993988. We project that, in aggregate, rural hospitals would experience a 0.2 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 2.7 percent increase in payments primarily due to the application of the rural floor in Massachusetts.

f. Effects of the Application of the Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and would increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and an estimated 44 hospitals located in those States would receive a frontier wage index of 1.0000. Overall, this provision is not budget

neutral and is estimated to increase IPPS operating payments by approximately $68 million.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment would receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 184 providers that would receive the out-migration wage adjustment in FY 2022. This out-migration wage adjustment is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $40 million.

g. Effects of All FY 2022 Proposed Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2021 and FY 2022, resulting from all changes reflected in this proposed rule for FY 2022. It includes combined effects of the year-to-year change of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 2.7 percent for FY 2022 relative to FY 2021 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 7 includes the proposed annual hospital update of 2.8 percent to the national standardized amount. This proposed annual hospital update includes the proposed 2.5 percent market basket update reduced by the proposed 0.2 percentage point multifactor productivity adjustment. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 2.3 percent hospital update. As described in Column 1, the proposed annual hospital update with the proposed +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates, would result in a 2.7 percent increase in payments in FY 2022 relative to FY 2021. There are interactive effects among the various factors comprising the payment system that we are not able to isolate, which contribute to our estimate of the proposed changes in payments per discharge from FY 2021 and FY 2022 in Column 7.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.7 percent for FY 2022. Hospitals in urban areas would experience a 2.7 percent increase in payments per discharge in FY 2022 compared to FY 2021. Hospital payments per discharge in rural areas are estimated to increase by 2.9 percent in FY 2022.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2022 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2021 with the estimated proposed average payments per discharge for FY 2022, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

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TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2022 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2021 Payment Per Discharge (2)	Estimated Proposed Average FY 2022 Payment Per Discharge (3)	Proposed FY 2022 Changes (4)
All Hospitals	3,198	13,106	13,459	2.7
By Geographic Location:				
Urban hospitals	2,459	13,452	13,812	2.7
Rural hospitals	739	9,897	10,186	2.9
Bed Size (Urban):				
0-99 beds	633	10,723	11,027	2.8
100-199 beds	755	11,014	11,312	2.7
200-299 beds	427	12,247	12,563	2.6
300-499 beds	421	13,490	13,851	2.7
500 or more beds	223	16,569	17,018	2.7
Bed Size (Rural):				
0-49 beds	313	8,544	8,886	4
50-99 beds	254	9,417	9,665	2.6
100-149 beds	94	9,790	10,041	2.6
150-199 beds	39	10,519	10,800	2.7
200 or more beds	39	11,465	11,811	3
Urban by Region:				
New England	112	14,839	15,165	2.2
Middle Atlantic	304	15,432	15,742	2
East North Central	381	12,839	13,200	2.8
West North Central	160	13,121	13,530	3.1
South Atlantic	402	11,711	12,073	3.1
East South Central	144	11,291	11,600	2.7
West South Central	364	11,793	12,100	2.6
Mountain	172	13,698	14,049	2.6
Pacific	370	17,228	17,722	2.9
Puerto Rico	50	8,480	8,650	2
Rural by Region:				
New England	19	13,990	14,482	3.5
Middle Atlantic	50	9,736	9,987	2.6
East North Central	114	10,358	10,620	2.5

	Number of Hospitals (1)	Estimated Average FY 2021 Payment Per Discharge (2)	Estimated Proposed Average FY 2022 Payment Per Discharge (3)	Proposed FY 2022 Changes (4)
West North Central	89	10,625	10,918	2.8
South Atlantic	114	9,030	9,323	3.2
East South Central	144	8,732	8,983	2.9
West South Central	136	8,289	8,504	2.6
Mountain	49	12,078	12,271	1.6
Pacific	24	13,865	14,622	5.5
By Payment Classification:				
Urban hospitals	1,965	12,790	13,128	2.6
Rural areas	1,233	13,582	13,959	2.8
Teaching Status:				
Nonteaching	2,034	10,673	10,976	2.8
Fewer than 100 residents	907	12,386	12,705	2.6
100 or more residents	257	18,938	19,450	2.7
Urban DSH:				
Non-DSH	505	11,736	12,042	2.6
100 or more beds	1,210	13,171	13,521	2.7
Less than 100 beds	350	9,535	9,812	2.9
Rural DSH:				
SCH	260	11,100	11,405	2.7
RRC	622	14,094	14,481	2.7
100 or more beds	34	14,327	14,691	2.5
Less than 100 beds	217	7,785	8,040	3.3
Urban teaching and DSH:				
Both teaching and DSH	674	14,280	14,651	2.6
Teaching and no DSH	74	12,572	12,821	2
No teaching and DSH	886	10,914	11,223	2.8
No teaching and no DSH	331	10,879	11,171	2.7
Special Hospital Types:				
RRC	555	14,259	14,659	2.8
SCH	304	12,082	12,407	2.7
MDH	148	9,137	9,389	2.8
SCH and RRC	151	12,529	12,837	2.5
MDH and RRC	24	10,575	10,817	2.3
Type of Ownership:				
Voluntary	1,883	13,317	13,668	2.6
Proprietary	828	11,472	11,796	2.8
Government	487	14,106	14,516	2.9
Medicare Utilization as a Percent of Inpatient Days:				
0-25	643	15,157	15,587	2.8
25-50	2,113	12,924	13,275	2.7
50-65	366	10,759	10,977	2
Over 65	51	8,116	8,387	3.3
FY 2022 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	1,048	13,575	13,947	2.7
Non-Reclassified Hospitals	2,150	12,699	13,037	2.7
Urban Hospitals Reclassified	860	14,091	14,464	2.6
Urban Nonreclassified Hospitals	1,612	12,855	13,204	2.7
Rural Hospitals Reclassified Full Year	304	10,081	10,356	2.7
Rural Nonreclassified Hospitals Full Year	422	9,606	9,920	3.3
All Section 401 Reclassified Hospitals:	550	14,656	15,059	2.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	9,149	9,432	3.1

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H. Effects of Other Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.G. of this Appendix A, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Proposed Policies Relating to New Medical Service and Technology Add-On Payments and New COVID–19 Treatments Add-on Payment (NCTAP)

a. Proposed FY 2022 Status of Technologies Approved for FY 2021 New Technology Add-On Payments

In section II.F.4. of the preamble of this proposed rule, we are proposing to continue to make new technology add-on payments for BAROSTIM NEO System, BALVERSA™, Jakafi®, FETROJA®, Optimizer® System, RECARBRIO™, Soliris®, XENLETA™, and ZERBAXA® in FY 2022 because these technologies would still be considered new for purposes of new technology add-on payments. We are also proposing a 1-year extension for FY 2022 of the new technology add-on payments for the following technologies, for which new technology add-on payments would otherwise be discontinued beginning with FY 2022: AndexXa™, AZEDRA®, Cablivi®, ContaCT, Eluvia Drug-Eluting Vascular Stent System, ELZONRIS®, Esketamine (SPRAVATO®), Hemospray, IMFINZI/TECENTRIQ, NUZYRA, Spinejack, T2 Bacteria Test Panel, XOSPATA®, and ZEMDRI™. We refer readers to section II.F. of the preamble of this proposed rule with regard to our proposal for a 1-year extension of new technology add-on payments for these technologies in FY 2022.

Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this proposed rule are based on applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2022 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. In the following table are estimates for the 23 technologies for which we are proposing to continue to make new technology add-on payments in FY 2022:

Technology Name	Estimated Cases	Proposed FY 2022 NTAP amount (65 % or 75 %)	Estimated Total FY 2022 Impact
Andexa Xa	5,402	$18,281.25	$98,755,312.50
Azedra	400	$98,150.00	$39,260,000.00
BAROSTIM NEO System	722	$22,750.00	$16,425,500.00
Caplacizumab	131	$33,215.00	$4,351,165.00
ContaCT	69,336	$1,040.00	$72,109,440.00
Erdafitinib (Balversa)	50	$3,563.23	$178,161.50
Esketamine (SPRAVATO)	6,400	$1,014.79	$6,494,656.00
Eluvia Drug-Eluting Vascular Stent System	2,453	$3,646.50	$8,944,864.50
Elzonris	247	$125,448.05	$30,985,668.35
FETROJA	6,355	$7,919.86	$50,330,710.30
Hemospray	12,700	$1,625.00	$20,637,500.00
IMFINZI/TECENTRIQ	4,296	$6,875.90	$29,538,866.40
Jakafi	140	$4,096.21	$573,469.40
NUZYRA	16,899	$1,552.50	$26,235,697.50
Optimizer System	1,500	$14,950.00	$22,425,000.00
RECARBRIO	762	$3,532.78	$2,691,978.36
Soliris	13,680	$21,199.75	$290,012,580.00
Spinejack	1,572	$3,654.72	$5,745,219.84
T2 Bacteria Test Panel	37639	$97.50	$3,669,802.50
XENLETA	35246	$1,275.75	$44,965,084.50
Xospata	1,875	$7,312.50	$13,710,937.50
ZERBAXA	30,117	$1,836.98	$55,324,326.66
Zemdri	2,500	$4,083.75	$10,209,375.00

b. Proposed FY 2022 Applications for New Technology Add-On Payments

In sections II.F.5. and 6. of the preamble to this proposed rule, we discuss 37 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2022. We note that five applicants withdrew their application prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.F.6. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are part of the

Breakthrough Device program will be considered new and not substantially similar to an existing technology and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still meet the cost criterion.

As also discussed in section II.F.6. of the preamble of this proposed rule, we are proposing to approve 14 of the 16 alternative pathway applications for FY 2022 new technology add-on payments. We note that for one technology, the 3-year anniversary date of the product's entry onto the U.S. market will occur in FY 2021, and therefore we do not believe that the device is eligible for new technology add-on payments for FY 2022. We also note that another technology does not appear to include any operating costs and therefore no new technology add-on payment would be made because, as discussed in prior rulemaking and noted previously, we only make new technology add-on payments for operating costs (72 FR 47307 and 47308).

Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the 16 technologies that applied under the alternative pathway, if approved, would be approximately $80 million for FY 2022. Total estimated FY 2022 payments for new technologies that are designated as a QIDP would be approximately $58 million, and total estimated FY 2022 payments for new technologies that are part of the Breakthrough Device program would be approximately $22 million. We note that these estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the 21 technologies that applied under the traditional pathway discussed in section II.F.5. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2022. Consequently, it is premature to estimate the potential payment impact of these 21 technologies for any potential new technology add-on payments for FY 2022. We note that, as in past years, if any of the 21 technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2022, in the FY 2022 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2022.

c. Proposed Changes to FY 2022 New COVID–19 Treatments Add-On Payment (NCTAP)

As discussed in section II.F. of the preamble of this proposed rule, in response to the COVID–19 PHE, we established the NCTAP under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 and 71158). In this proposed rule we are proposing to extend the NCTAP for eligible products that are not approved for new technology add-on payments through the end of the fiscal year in which the PHE ends (for example, September 30, 2022). We also are proposing to discontinue the NCTAP for discharges on or after October 1, 2021 for a product that is approved for new technology add-on payments beginning FY 2022.

Given that it is unknown what the cost and utilization of inpatient stays using these new treatments will be, the net overall cost of the proposed extension of the NCTAP is not estimable. On one extreme, if all of the new COVID–19 treatments decrease the net cost of hospitalizations (for example, due to shortened lengths of stay), including the cost of the new treatment, below the Medicare payment for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, then there would be no NCTAP made and no additional cost to the Medicare program as a result of this proposed extension. On the other extreme, if all of the new COVID–19 treatments result in the net cost of hospitalizations that exceed the outlier threshold (for example, due to the cost of the new treatment) for discharges after the end of the PHE and through the end of the fiscal year in which the PHE ends, the cost to the Medicare program would be the sum over all such NCTAP cases of 0.65 times the outlier threshold for each case.

2. Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2022

a. Proposed Revision of the Regulations To Ensure Only Appropriate Days Are Counted in the Numerator of the Medicaid Fraction

As discussed in section V.F. of the preamble of this proposed rule, we are proposing to revise the regulation governing the DSH calculation to ensure that the only section 1115 days that may be counted in the numerator of the Medicaid fraction are the days of patients for whom a section 1115 waiver provides inpatient hospital insurance coverage benefits directly to that patient on that day. To the extent that this proposal has an impact on expenditures, that impact is not estimable because we do not have information on the number of section 1115 days by hospital, which would be required to make an estimate.

b. Medicare DSH Uncompensated Care Payment Proposals for FY 2022

As discussed in section V.E. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2022 is $7,627,628,282.10. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 72.14 percent. For FY 2021, the amount available to be distributed for uncompensated care was $8,290,014,520.96 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 72.86 percent. Consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule for FY 2022 and subsequent fiscal years, we will use a single year of data on uncompensated care costs from Worksheet S–10 of the FY 2018 cost reports to calculate Factor 3 in the FY 2022 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico Hospitals. To calculate Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are proposing to use data regarding Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available SSI days (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data). For a complete discussion of the proposed methodology for calculating Factor 3, we refer readers to section V.E.4. of the preamble of this proposed rule.

To estimate the impact of the combined effect of proposed changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments, we compared total uncompensated care payments estimated in the FY 2021 IPPS/LTCH PPS final rule to total uncompensated care payments estimated in this FY 2022 IPPS/LTCH PPS proposed rule. For FY 2021, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 72.86 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2021 IPPS/LTCH PPS final rule. For FY 2022, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a proposed Factor 2 of 72.14 percent and multiplied by a Factor 3 calculated using the methodology described previously.

Our analysis included 2,378 hospitals that are projected to be eligible for DSH in FY 2022. It did not include hospitals that had terminated their participation from the Medicare program as of January 28, 2021, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. The 27 hospitals participating in the Rural Community Hospital Demonstration Program were excluded from this analysis, as

participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the proposed changes in Factors 1, 2, and 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2022, by hospital characteristic, is presented in the following table.

Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2021 to FY 2022

	Number of Estimated DSHs (1)	FY 2021 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2022 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2021 - FY 2022 ($ in millions) (4)	Percent Change** (5)
Total	**2,378**	**$8,290**	**$7,628**	**-$662**	**-7.99%**
By Geographic Location					
Urban Hospitals	1,911	7,803	7,195	-608	-7.79
Large Urban Areas	991	4,829	4,381	-448	-9.27
Other Urban Areas	920	2,974	2,814	-160	-5.37
Rural Hospitals	467	487	432	-55	-11.27
Bed Size (Urban)					
0 to 99 Beds	331	290	262	-28	-9.61
100 to 249 Beds	823	1,898	1,700	-198	-10.42
250+ Beds	757	5,615	5,233	-382	-6.80
Bed Size (Rural)					
0 to 99 Beds	353	269	231	-38	-14.02
100 to 249 Beds	100	166	150	-16	-9.86
250+ Beds	14	52	51	-1	-1.57
Urban by Region					
New England	93	227	199	-28	-12.14
Middle Atlantic	236	983	868	-115	-11.66
South Atlantic	313	864	847	-17	-1.97
East North Central	99	405	375	-29	-7.29
East South Central	313	2,027	1,860	-167	-8.24
West North Central	129	498	464	-34	-6.90
West South Central	242	1,637	1,529	-108	-6.60
Mountain	132	333	315	-18	-5.27
Pacific	315	723	642	-81	-11.19
Puerto Rico	39	107	96	-11	-10.20
Rural by Region					
New England	8	15	16	1	4.68
Middle Atlantic	22	15	14	-2	-10.59
South Atlantic	65	58	46	-12	-20.88
East North Central	29	31	26	-4	-14.58

Modeled Uncompensated Care Payments for Estimated FY 2022 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2021 to FY 2022					
	Number of Estimated DSHs (1)	FY 2021 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2022 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2021 - FY 2022 ($ in millions) (4)	Percent Change** (5)
East South Central	84	135	129	-6	-4.46
West North Central	123	102	89	-13	-13.14
West South Central	108	105	93	-12	-11.17
Mountain	23	19	15	-5	-24.47
Pacific	5	7	5	-1	-21.22
By Payment Classification					
Urban Hospitals	1,498	5,429	5,016	-413	-7.61
Large Urban Areas	834	3,540	3,240	-300	-8.47
Other Urban Areas	664	1,890	1,776	-113	-5.99
Rural Hospitals	880	2,861	2,611	-249	-8.72
Teaching Status					
Nonteaching	1,381	2,444	2,260	-185	-7.55
Fewer than 100 residents	744	2,869	2,639	-230	-8.01
100 or more residents	253	2,977	2,729	-248	-8.33
Type of Ownership					
Voluntary	1,433	4,556	4,221	-334	-7.34
Proprietary	575	1,217	1,139	-78	-6.40
Government	370	2,517	2,267	-250	-9.94
Medicare Utilization Percent***					
0 to 25	554	3,388	3,108	-280	-8.27
25 to 50	1,613	4,707	4,355	-352	-7.48
50 to 65	188	189	160	-29	-15.17
Greater than 65	22	6	4	-2	-27.46

Source: Dobson | DaVanzo analysis of 2013 and 2018 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $8,290 million in FY 2021 and $7,628 million in FY 2022.

** Percentage change is determined as the difference between Medicare uncompensated care payments modeled for this FY 2022 IPPS/LTCH PPS proposed rule (column 3) and Medicare uncompensated care payments modeled for the FY 2021 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2021 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

***Hospitals with missing or unknown Medicare utilization are not shown in table.

The changes in projected FY 2022 uncompensated care payments from payments in FY 2021 are driven by a proposed decrease in Factor 1 and a proposed decrease in Factor 2, as well as by a decrease in the number of hospitals projected to be eligible to receive DSH in FY 2022 relative to FY 2021. The proposed Factor 1 has decreased from FY 2021 final rule's Factor 1 of $11.378 billion to this proposed rule's Factor 1 of $10.573 billion, while the proposed percent change in the percent of individuals who are uninsured (Factor 2) has decreased from 72.86 percent to 72.14 percent. Based on the proposed changes in these two factors, the impact analysis found that, across all projected DSH eligible hospitals, proposed FY 2022 uncompensated care payments are estimated at approximately $7.628 billion, or a proposed decrease of approximately 7.99 percent from FY 2021 uncompensated care payments (approximately $8.290 billion). While these proposed changes would result in a net decrease in the amount available to be distributed in uncompensated care payments, the projected payment decreases vary by hospital type. This redistribution of uncompensated care payments is caused by proposed changes in Factor 3. As seen in the previous table, a percent change of less than negative 7.99 percent indicates that hospitals within the specified category are projected to experience a larger decrease in uncompensated care payments, on average, compared to the universe of projected FY 2022 DSH hospitals. Conversely, a percent change greater than negative 7.99 percent indicates that a hospital type is projected to have a smaller decrease than the overall average. Similarly, a positive percent change indicates an increase in uncompensated care payments. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported in the Worksheet S–10, or number of Medicaid days and SSI days for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, used in the Factor 3 computation.

Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive an 11.27 percent decrease in uncompensated care payments, while urban hospitals are projected to receive a 7.79 percent decrease in uncompensated care payments.

By bed size, smaller rural hospitals are projected to receive the largest decreases in uncompensated care payments. Rural hospitals with 0–99 beds are projected to receive a 14.02 percent payment decrease, and rural hospitals with 100–249 beds are projected to receive a 9.86 percent decrease. These decreases for smaller rural hospitals are greater than the overall hospital average. However, larger rural hospitals with 250+ beds are projected to receive a smaller than average payment decrease of 1.57 percent. This trend is consistent among urban hospitals, with the smallest urban hospitals, those with 0–99 and 100–249 beds, projected to receive a decrease in uncompensated care payments that is greater than the overall hospital average, at 9.61 and 10.42 percent, respectively. In contrast, the largest urban hospitals with 250+ beds are projected to receive a 6.80 percent decrease in uncompensated care payments, which is a smaller decrease than the overall hospital average.

By region, rural hospitals are expected to receive larger than average decreases in uncompensated care payments in all Regions, except for rural hospitals in New England, which are projected to receive an increase of 4.68 percent in uncompensated care payments, and rural hospitals in the East South Central Region, which are projected to receive a smaller than average decrease of 4.46 percent. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, Middle Atlantic, East South Central, and Pacific Regions, as well as urban hospitals in Puerto Rico, are projected to receive larger than average decreases in uncompensated care payments. Urban hospitals in the South Atlantic, East North Central, West North Central, West South Central, and Mountain Regions are projected to receive smaller than average decreases in uncompensated care payments.

By payment classification, although hospitals in urban areas overall are expected to receive a 7.61 percent decrease in uncompensated care payments, hospitals in large urban areas are expected to see a decrease in uncompensated care payments of 8.47 percent, while hospitals in other urban areas are expected to receive a decrease in uncompensated care payments of 5.99 percent. Rural hospitals are projected to receive the largest decrease of 8.72 percent.

Nonteaching hospitals are projected to receive a payment decrease of 7.55 percent, teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 8.01 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 8.33 percent. All of these decreases closely approximate the overall hospital average. Proprietary and voluntary hospitals are projected to receive smaller than average decreases of 6.40 and 7.34 percent respectively, while government hospitals are expected to receive a larger payment decrease of 9.94 percent. All hospitals with less than 50 percent Medicare utilization are projected to receive decreases in uncompensated care payments consistent with the overall hospital average percent change, while hospitals with 50–65 percent and greater than 65 percent Medicare utilization are projected to receive larger decreases of 15.17 and 27.46 percent, respectively.

3. Effects of Proposed Reductions Under the Hospital Readmissions Reduction Program for FY 2022

In section V.G. of the preamble of this proposed rule, we discuss our proposed policies for the FY 2022 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this proposed rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. For the purpose of modeling the proposed FY 2022 payment adjustment factors for this proposed rule, we used the payment adjustment factors from the FY 2021 Hospital Readmissions Reduction Program and the FY 2021 Hospital IPPS proposed rule Impact File to analyze results by hospital characteristics. Hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2016 and June 30, 2019 (that is, the FY 2021 Hospital Readmissions Reduction Program's performance period). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. In the FY 2022 IPPS/LTCH PPS final rule, we will provide an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2022 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2017 through June 30, 2020). We note that for the FY 2022 applicable period, we will only be assessing data from July 1, 2017 through December 1, 2019 due to the COVID–19 public health emergency (PHE) nationwide Extraordinary Circumstance Exception (ECE) waiver which excluded data from January 1, 2020 through June 30, 2020 from the Hospital Readmissions Reduction Program calculations.[1527]

The results in the table include 2,986 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2016 and June 30, 2019. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 82.17 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 89.70 percent of eligible hospitals with fewer than 100 residents and 92.64 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristic. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2018 and September 30, 2019 (FY 2019). For example, the penalty as a share of payments for urban hospitals is 0.68 percent. This means that total penalties for all urban hospitals are 0.68 percent of total payments for urban hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

[1527] Although the FY 2022 applicable period is July 1, 2017 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for scoring purposes due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments would be adjusted to July 1, 2017 through December 1, 2019. Further information will be found in the FY 2022 Hospital Specific Report (HSR) User Guide located on QualityNet website at: *https://qualitynet.cms.gov/inpatient/hrrp/reports* that is anticipated to become available in August 2021.

Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2022 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a Share of Payments[d] (%)**
All Hospitals	2,986	2,545	85.23	0.68
By Geographic Location (n= 2,985)[e]				
Urban hospitals	2,256	1,958	86.79	0.68
1-99 beds	516	369	71.51	0.84
100-199 beds	698	634	90.83	0.83
200-299 beds	417	386	92.57	0.76
300-399 beds	265	243	91.70	0.67
400-499 beds	140	125	89.29	0.61
500 or more beds	220	201	91.36	0.54
Rural hospitals	729	586	80.38	0.68
1-49 beds	290	212	73.10	0.60
50-99 beds	260	209	80.38	0.71
100-149 beds	96	87	90.63	0.60
150-199 beds	44	40	90.91	0.68
200 or more beds	39	38	97.44	0.73
By Teaching Status[f] (n= 2,985)				
Non-teaching	1,873	1,539	82.17	0.79
Fewer than 100 residents	854	766	89.70	0.69
100 or more residents	258	239	92.64	0.50
By Ownership Type (n= 2,985)				
Government	460	383	83.26	0.52
Proprietary	740	595	80.41	1.02
Voluntary	1,785	1,566	87.73	0.63
By Safety-net Status[g] (n= 2,985)				
Safety-net hospitals	592	519	87.67	0.56
Non-safety-net hospitals	2,393	2,025	84.62	0.71
By Disproportionate Share Hospital (DSH) Patient Percentage[h] (n= 2,985)				
0-24	1,231	1,005	81.64	0.77
25-49	1,414	1,243	87.91	0.63
50-64	194	167	86.08	0.67
65 and over	146	129	88.36	0.52
By Medicare Cost Report (MCR) Percentage[i] (n= 2,976)				
0-24	480	412	85.83	0.49
25-49	2,070	1,782	86.09	0.69
50-64	374	310	82.89	0.93
65 and over	52	35	67.31	0.48
By Region (n= 2,985)				
New England	125	113	90.40	0.92
Middle Atlantic	339	317	93.51	0.74
South Atlantic	502	459	91.43	0.74
East North Central	468	394	84.19	0.66
East South Central	274	241	87.96	0.82
West North Central	240	187	77.92	0.44
West South Central	459	380	82.79	0.67
Mountain	217	161	74.19	0.53
Pacific	361	292	80.89	0.50

Source: The table results are based on the FY 2021 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2021 payment adjustment factors are based on discharges between July 1, 2016 and June 30, 2019 (the FY 2021 Hospital Readmissions Reduction Period performance period). Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2020 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are stratified into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the 3-year performance period. Hospital characteristics are from the FY 2021 Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule Impact File.

For the FY 2022 applicable period, CMS will only be assessing data from July 1, 2017 through December 1, 2019 due to the COVID-19 public health emergency (PHE) nationwide Extraordinary Circumstances Exception (ECE) waiver which excluded data from January 1, 2020 through June 30, 2020 from the Hospital Readmissions Reduction Program (HRRP) calculations. We expect that there would be a minimal impact on hospitals when 6 months of data are removed from Hospital Readmissions Reduction Program calculations.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).
[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.
[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.
[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. MedPAR data from October 1, 2018 through September 30, 2019 (FY 2019), are used to estimate the total base operating DRG payments.
[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location (n=2,985; missing=1), teaching status (n=2,985; missing=1), ownership type (n=2,985; missing=1), safety-net status (n=2,985; missing=1), DSH patient percentage (n=2,985; missing=1), MCR percentage (n=2,976; missing=10), and region (n=2,985; missing=1).
[f] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.
[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.
[h] DSH [Disproportionate Share Hospital] patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.
[i] MCR [Medicare Cost Report] percentage is the percentage of total inpatient stays from Medicare patients.

4. Effects of Proposed Changes Under the FY 2022 Hospital Value-Based Purchasing (VBP) Program

In section V.H. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. We are proposing to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey, Medicare Spending Per Beneficiary (MSPB) and five healthcare-associated infection (HAI) measures, as well as to change the scoring and payment methodologies for the FY 2022 program year, such that the hospital would receive a value-based incentive payment percentage that results in a value-based incentive payment amount that is equal to the applicable percentage (2 percent). Specifically, we are proposing that we will calculate the measure rates for all of the measures we have selected for the FY 2022 program year, but that we would not generate achievement or improvement points for any of the measures we are proposing to suppress. Additionally, we are proposing to not award domain scores for the Person and Community Engagement, Efficiency and Cost Reduction, and Safety domains. Therefore, we would not award hospitals a TPS, and would instead award hospitals a payment incentive multiplier that results in a value-based incentive payment amount that is equal to the amount withheld for the fiscal year (2 percent). That is, each hospital would receive a 2 percent reduction to its base operating DRG payment amount for each FY 2022 discharge and will then receive a value-based incentive payment percentage that will result in a value-based incentive payment amount that is equal to the 2 percent withheld. If these proposals are finalized, the impact for every hospital under the Hospital VBP Program would be a net percentage payment adjustment of zero.

We are also providing the estimated impact of the FY 2022 program because those impacts would apply if the proposals, as previously discussed, are not finalized. We used TPSs from FY 2021 to calculate the proxy adjustment factors used for this impact analysis. We note that these FY 2021 TPSs were calculated using measure data from before the COVID–19 PHE was declared, and that if our proposals are not finalized, actual TPSs for the FY 2022 program year could be more variable than the FY 2021 TPSs due to the impacts of the COVID–19 PHE on FY 2022 data. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2020 update to the FY 2020 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website). This impact analysis shows that, for the FY 2022 program year, the number of hospitals that would receive an increase in their base operating DRG payment amount is lower than the number of hospitals that would receive a decrease. On average, urban hospitals in the New England region and rural hospitals in the East South Central region would have the highest positive percentage change in base operating DRG. Hospitals in the Urban Middle Atlantic, Urban South Atlantic, Urban West South Central, Rural New England, Rural Middle Atlantic, Rural South Atlantic, and Rural West South Central regions would experience an average negative percent change in base operating DRG. All other regions, both urban and rural, would experience an average positive percent change in base operating DRG payment amounts.

As DSH patient percent increases, the average percent change in the base operating DRG payment amounts would generally increase (excluding DSH Percent = 50–65, for which the average percent change in the base operating DRG payment amounts would be lower than the average percent change in the base operating DRG payment amounts for all

other categories). With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the average percent change in the base operating DRG payment amounts would generally increase. On average, non-teaching hospitals would have a lower percentage change in their base operating DRG payment amounts compared to teaching hospitals; however, on average, both non-teaching hospitals and teaching hospitals would have a positive percentage change in their base operating DRG payment amounts.

Estimated Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2022 Hospital VBP Program if Proposals Are Not Finalized			
		Number of Hospitals	**Average Net Percentage Payment Adjustment**
BY GEOGRAPHIC LOCATION:			
	All Hospitals	2676	0.039
	Large Urban	2064	0.021
	Other Urban	N/A	N/A
	Rural Area	612	0.097
	Urban hospitals	2064	0.021
	0-99 beds	338	0.069
	100-199 beds	687	0.065
	200-299 beds	414	-0.008
	300-499 beds	407	-0.039
	500 or more beds	218	-0.022
	Rural hospitals	612	0.097
	0-49 beds	203	0.058
	50-99 beds	242	0.082
	100-149 beds	90	0.186
	150-199 beds	39	0.166
	200 or more beds	38	0.118
BY REGION:			
	Urban By Region	2064	0.021
	New England	103	0.117
	Middle Atlantic	273	-0.007
	South Atlantic	373	-0.078

Estimated Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2022 Hospital VBP Program if Proposals Are Not Finalized			
		Number of Hospitals	Average Net Percentage Payment Adjustment
	East North Central	333	0.104
	East South Central	120	0.016
	West North Central	133	0.082
	West South Central	251	-0.040
	Mountain	145	0.078
	Pacific	333	0.044
	Rural By Region	612	0.097
	New England	18	-0.173
	Middle Atlantic	45	-0.020
	South Atlantic	94	-0.086
	East North Central	106	0.090
	East South Central	108	0.297
	West North Central	76	0.234
	West South Central	94	-0.024
	Mountain	47	0.156
	Pacific	24	0.287
By MCR Percent			
	0-25	493	0.004
	25-50	1888	0.042
	50-65	284	0.068
	Over 65	10	0.100
	Missing	1	1.391
BY DSH Percent:			
	0-25	1040	0.027
	25-50	1339	0.049
	50-65	167	-0.013
	Over 65	130	0.095
BY TEACHING STATUS:			
	Non-Teaching	1570	0.032
	Teaching	1106	0.048

The actual FY 2022 program year's TPSs would not be reviewed and corrected by hospitals until after the FY 2022 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2021 program year would be used for the updated impact analysis in the final rule, if the proposals, as previously described, for FY 2022 are not finalized.

We note that we are also proposing to suppress the MORT–30–PN measure for the FY 2023 program year. If this proposal is finalized, we would calculate the measure rate for the MORT–30–PN program year,

however, we would not generate achievement or improvement points for that measure. At this time, we have not proposed to suppress any other measures for the FY 2023 program year. Therefore, we are not proposing any changes to the scoring methodology for the FY 2023 program in this proposed rule. Hospitals will still receive achievement and improvement points on the remaining measures for which they report the minimum number of cases, and they will receive scores on domains for which they report the minimum number of measures for the FY 2023 program year. The domain scores, weighted at 25 percent each, will be used to calculate TPSs for the FY 2023 program year. We are also proposing to remove the CMS PSI 90 measure beginning with the FY 2023 program year. However, because we are proposing to remove this measure before it would be used in calculating a hospital's TPS under the Hospital VBP Program, we do not expect this proposal will have impacts for the FY 2023 program year.

5. Effects Under the HAC Reduction Program for FY 2022

We are presenting the estimated impact of the FY 2022 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic in the following two tables. These FY 2022 HAC Reduction Program results were calculated using the Equal Measure Weights approach finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41486 through 41489). Each hospital's Total HAC Score was calculated as the equally weighted average of the hospital's measure scores. The tables in this section present the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. The first table shows the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores using the proposed one-year performance period for the HAI measures if the measure suppression policy proposed in section IX.I.3.d. of the preamble of this proposed rule is finalized and adopted for the FY 2022 program year. The second table shows the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores using the previously finalized two-year performance period for the HAI measures.

The first table calculates hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results based on Medicare fee-for-service (FFS) discharges from July 1, 2016 and December 31, 2017 and version 9.0 of the PSI software. Hospitals' measure results for the Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) measures are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2017 and December 31, 2017. These results are based on the FY 2020 Final Rule Impact Table and estimate the impacts of the measure suppression policy by excluding 6 months of CMS PSI 90 data and 12 months of CDC measure data. For the second table, hospitals' CMS PSI 90 measure results are based on Medicare fee-for-service (FFS) discharges from July 1, 2018 through December 31, 2019 [1528] and version 11.0 of the PSI software. Hospitals' measure results for CDC CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA bacteremia, and CDI measures are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2018 and December 31, 2019. To analyze the results by hospital characteristic, we used the FY 2021 Final Rule Impact File. Both tables are based on historical data and may not reflect the actual impacts of the COVID–19 PHE.

While both tables are presented in this section and their format is the same, we use values from the first table in this text as an examples because the length of data periods match the measure suppression policy proposed in section IX.I.3.d. of the preamble of this proposed rule. The table includes 3,169 non-Maryland hospitals with a FY 2022 Total HAC Score. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2022 HAC Reduction Program. For example, with regard to teaching status, 475 hospitals out of 1,988 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 199 out of 891 hospitals with fewer than 100 residents and 103 out of 260 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2022 HAC Reduction Program. For example, 23.9 percent of the 1,988 hospitals characterized as non-teaching hospitals, 22.3 percent of the 891 teaching hospitals with fewer than 100 residents, and 39.6 percent of the 260 teaching hospitals with 100 or more residents would be subject to a payment reduction.

[1528] Although the FY 2022 applicable period for the CMS PSI 90 measure is July 1, 2018 through June 30, 2020, we note that first and second quarter data from CY 2020 is excluded from consideration for scoring purposes due to the nationwide ECE that was granted in response to the COVID–19 public health emergency. CMS, ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' 85 FR 54820.

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2022 HAC Reduction Program (by Hospital Characteristic) if the Measure Suppression Policy in Section IX.I.3.d. is Finalized			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,169	791	25
By Geographic Location (n = 3,139)[d]			
Urban hospitals	2,384	572	24
1-99 beds	600	123	20.5
100-199 beds	725	172	23.7
200-299 beds	418	112	26.8
300-399 beds	279	70	25.1
400-499 beds	139	36	25.9
500 or more beds	223	59	26.5
Rural hospitals	755	205	27.2
1-49 beds	323	91	28.2
50-99 beds	259	78	30.1
100-149 beds	95	18	18.9
150-199 beds	39	10	25.6
200 or more beds	39	8	20.5
By Safety-Net Status[e] (n = 3,139)			
Non-safety net	2,499	563	22.5
Safety-net	640	214	33.4
By DSH Percent[f] (n = 3,139)			
0-24	1,312	272	20.7
25-49	1,462	370	25.3
50-64	199	76	38.2
65 and over	166	59	35.5
By Teaching Status[g] (n =3,139)			
Non-teaching	1,988	475	23.9
Fewer than 100 residents	891	199	22.3
100 or more residents	260	103	39.6
By Ownership[h] (n = 3,139)			
Voluntary	1,851	444	24
Proprietary	806	180	22.3
Government	482	153	31.7
By MCR Percent[i] (n = 3,136)			
0-24	595	160	26.9
25-49	2,120	501	23.6
50-64	373	102	27.3
65 and over	48	13	27.1
By Region[j] (n= 3,169)			
New England	131	34	26

Mid-Atlantic	358	101	28.2
South Atlantic	518	137	26.4
East North Central	491	118	24
East South Central	292	69	23.6
West North Central	253	57	22.5
West South Central	503	113	22.5
Mountain	227	55	24.2
Pacific	396	107	27

Source: FY 2022 HAC Reduction Program proposed rule results are based on CMS PSI 90 data from July 1, 2016 through December 31, 2018 and CDC NHSN HAI results from January 1, 2018 through December 31, 2018. Hospital Characteristics are based on the FY 2021 Proposed Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2022 Total HAC Score (N = 3,169). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, and teaching status (n = 3,139).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 3,139).

[i] Not all hospitals had data for MCR percent (n = 3,136).

[j] All hospitals had data for Region (n = 3,169).

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2022 HAC Reduction Program (by Hospital Characteristic) if the Measure Suppression Policy in Section IX.I.3.d. is Not Finalized			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-performing Quartile[b]**
Total[c]	3,075	768	25
By Geographic Location (n = 3,070)[d]			
Urban hospitals	**2,334**	**585**	**25.1**
1-99 beds	575	107	18.6
100-199 beds	707	177	25
200-299 beds	417	106	25.4
300-399 beds	275	69	25.1
400-499 beds	138	42	30.4
500 or more beds	222	84	37.8
Rural hospitals	**736**	**180**	**24.5**
1-49 beds	312	84	26.9
50-99 beds	252	51	20.2
100-149 beds	94	23	24.5
150-199 beds	39	12	30.8
200 or more beds	39	10	25.6
By Safety-Net Status[e] (n = 3,070)			
Non-safety net	2,452	550	22.4
Safety-net	618	215	34.8
By DSH Percent[f] (n = 3,070)			
0-24	1,280	263	20.5
25-49	1,437	379	26.4
50-64	194	63	32.5
65 and over	159	60	37.7
By Teaching Status[g] (n =3,070)			
Non-teaching	1,936	430	22.2
Fewer than 100 residents	876	211	24.1

100 or more residents	258	124	48.1
By Ownership[h] (n = 3,070)			
Voluntary	1,825	432	23.7
Proprietary	775	161	20.8
Government	470	172	36.6
By MCR Percent[i] (n = 3,063)			
0-24	583	158	27.1
25-49	2,084	496	23.8
50-64	356	99	27.8
65 and over	40	8	20
By Region[j] (n= 3,075)			
New England	130	46	35.4
Mid-Atlantic	342	99	28.9
South Atlantic	507	134	26.4
East North Central	482	114	23.7
East South Central	281	71	25.3
West North Central	244	61	25
West South Central	478	95	19.9
Mountain	229	56	24.5
Pacific	382	92	24.1

Source: FY 2022 HAC Reduction Program proposed rule results are based on CMS PSI 90 data from July 1, 2018 through December 31, 2019 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 1, 2018 through December 31, 2019. Hospital Characteristics are based on the FY 2021 Proposed Rule Impact File

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2022 Total HAC Score (N = 3,075). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, and teaching status (n = 3,070).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 3,070).

[i] Not all hospitals had data for MCR percent (n = 3,063).

[j] All hospitals had data for Region (n = 3,075).

6. Effects of the Proposed Changes to IME and Direct GME Payments

The Consolidated Appropriations Act (CAA) of 2020 contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals. Section 126 of the CAA makes available 1,000 new Medicare-funded GME positions, with 200 slots to be distributed in 5 rounds over 5 years starting in FY 2023, with priority given to hospitals in 4 categories. Section 127 of the CAA, effective for cost reporting periods beginning on or after October 1, 2022, makes changes relating to the determination of both an urban and rural hospital's FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track, and the application of the 3-year rolling average to the payment calculation of these hospitals. Section 131 of the CAA makes changes to the determination of direct GME PRAs and direct GME and IME FTE resident limits of hospitals that hosted a small number of residents for a short duration, based on new programs started on or after enactment (December 27, 2020) and 5 years after (December 26, 2025). We provide detailed proposals for implementing these 3 CAA provisions in section V.J.2. of this proposed rule. Following is a table showing the estimated cost of implementation of these 3 CAA provisions:

Cost Impact of CAA 2021 GME Provisions (in $millions)			
FY	**Section 126**	**Section 127**	**Section 131**
2021	0	0	10
2022	0	0	30
2023	10	0	60
2024	60	10	90
2025	120	10	130
2026	180	10	150
2027	240	20	170
2028	290	20	180
2029	300	20	180
2030	310	20	190
2031	320	20	190

In section V.J.2.d. of the preamble of this proposed rule, we also are proposing that, effective for cost reporting periods beginning on or after October 1, 2021, a cost report is rejected for teaching hospitals for lack of supporting documentation if it does not include the IRIS data that contains the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the teaching hospital's cost report. This proposal would continue to require all teaching hospitals to submit the IRIS data under § 413.24(f)(5) to have an acceptable cost report submission. However, this proposal would require that this data must correspond to the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the teaching hospital's cost report. Providers are required under §§ 413.20 and 413.24 to maintain data that substantiates their costs. IRIS is the source document for reporting FTEs in all teaching hospitals' cost reports. To enhance the contractors' ability to review duplicates and to ensure residents are not being double counted, we believe it is necessary and appropriate to require that the total unweighted and weighted FTE counts on the IRIS for direct GME and IME respectively, for all applicable allopathic, osteopathic, dental, and podiatric residents that a hospital may train, must equal the same total unweighted and weighted FTE counts for direct GME and IME reported on Worksheet E–4 and Worksheet E, Part A. Because all teaching hospitals are already required to submit the IRIS data under § 413.24(f)(5) to have an acceptable cost report submission, there are no additional burdens or expenses placed upon teaching hospitals as a result of our proposal to require that the supporting documents submitted (the IRIS data) correspond to the amounts reported in the cost report in order to have an acceptable cost report submission.

7. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2022

In section V.K. of the preamble of this proposed rule for FY 2022, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the current extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019. Therefore, we interpret the statute as providing for an additional 5-year period under the reasonable cost-based reimbursement methodology for the demonstration for the hospitals that were participating as of this date.

Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). We propose to adopt the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this proposed rule, the resulting amount applicable to FY 2022 is $63,829,479, which we are proposing to include in the budget neutrality offset adjustment for FY 2022. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we will continue this general procedure. All finalized cost reports are not yet all available for the 18 hospitals that completed a cost reporting period beginning in FY 2016 according to the demonstration cost-based payment methodology. We are expecting to include in the FY2022 IPPS/LTCH PPS final rule the difference between the actual costs of the demonstration as determined from these cost repots and the estimated costs as determined in the FY 2016 final rule.

For this proposed rule for FY 2022, the total amount that we are applying to the national IPPS rates is $63,829,479.

8. Effects of the Proposed Repeal of the Market-Based MS–DRG Relative Policy

In section V.L. of the preamble of this proposed rule, we are proposing to repeal the requirement that a hospital report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021, as finalized in the FY 2021 IPPS/LTCH PPS final rule. We are also proposing to repeal the market-based MS–DRG relative weight methodology that was adopted effective for FY 2024, as finalized in the FY 2021 IPPS/LTCH PPS final rule. In the FY 2021 IPPS/LTCH PPS final rule, we estimated the total annual burden hours for this data collection requirement as follows: 20 hours per hospital times 3,189 total hospitals equals 63,780 annual burden hours and $4,315,993 annually for all hospitals nationally. We refer readers to 85 FR 59015 for further analysis of this assessment.

The market-based MS–DRG relative weight methodology, as finalized in the FY 2021 IPPS/LTCH PPS final rule, is effective beginning with the relative weights calculated for FY 2024. If we were to finalize our proposal to repeal the market-based MS–DRG relative weight methodology effective in FY 2024, we would continue calculating the MS–DRG relative weights using the current cost-based MS–DRG relative weight methodology for FY 2024 and subsequent fiscal years. If finalized, this proposed repeal of the market-based data collection and market-based relative weight methodology would not result in a payment impact to hospitals and would instead decrease burden for hospitals required to comply with the market-based MS–DRG relative weight data collection requirement.

9. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VII.B.2. of the preamble of this proposed we discuss the implementation of the FCHIP demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for the demonstration described in the preamble of this rule are based on the time period from August 1, 2016 through July 31, 2019 (referred to in this section as the ''initial period'' of the demonstration). Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extends the FCHIP Demonstration by 5 years (referred to in this section as the ''extension period'' of the demonstration). Thus, the FCHIP Demonstration will resume on July 1, 2021, and CAHs participating in the demonstration project during the extension period shall begin such participation in the cost reporting year that begins on or after July 1. The initial period of the demonstration included three intervention prongs, under which specific waivers of Medicare payment rules allowed for enhanced payment: Telehealth, skilled nursing facility/nursing facility services, and ambulance services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. (We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42427 and 42428) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 588894 through 58896), but did not make any changes to the policy that was adopted in FY 2017.)

We specified the payment enhancements for the demonstration initial period and selected CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, in the FY 2017 IPPS/LTCH PPS final rule we adopted a contingency plan (81 FR 57064 through 57065) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 would be met. Accordingly, if analysis of claims data for the Medicare beneficiaries receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, shows that increases in Medicare payments under the demonstration during the 3-year initial period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration was projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAHs. Therefore, we will make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by this provider category. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Under the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years, beginning in CY 2020. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58895), we stated that based on the currently available data, the determination of budget neutrality results was preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remained uncertain. Therefore, we revised the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment and stated that we would revisit this policy in rulemaking for FY 2022, when we expected to have complete data for the demonstration period. Based on the data and actuarial analysis described previously, we have concluded the initial period of the FCHIP demonstration (covering the time period August 1, 2016, to July 31, 2019) has satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, we are not proposing to apply a budget neutrality payment offset to payments to CAHs in FY 2022. This policy will have no impact for any national payment system for FY 2022.

10. Effects of the Proposed Policy Regarding Medicaid Enrollment of Medicare Providers and Suppliers for Purposes of Processing Claims for Cost Sharing for Services Furnished to Dually Eligible Beneficiaries

In section X.A. of the preamble of this proposed rule, we discuss our proposals regarding Medicaid enrollment of Medicare providers and suppliers for purposes of processing claims for cost sharing for services furnished to dually eligible beneficiaries.

Under section 1902(a)(10)(E) of the Act, states are liable for Medicare cost-sharing amounts for certain beneficiaries dually eligible for Medicare and Medicaid, including those in the Qualified Medicare Beneficiary (QMB) program. Per section 1905(p)(3) of the Act, this cost-sharing liability includes costs incurred with respect to a QMB regardless of whether the costs incurred were for items and services covered under the Medicaid State plan.

All states require providers to enroll in Medicaid in order to process a Medicaid claim, including one for Medicare cost-sharing. However, some Medicare providers and suppliers have experienced difficulty enrolling in a State's Medicaid program and submitting claims for payment of Medicare cost-sharing.

Because some states at times have not met their obligation at section 1905(p)(3) of the Act to determine Medicare cost-sharing liability, we are proposing to add a new paragraph (d) to 42 CFR 455.410 to specify, in part, how states must meet this obligation. Specifically, we propose that by January 1, 2023, for purposes of determining Medicare cost-sharing liability, State Medicaid programs must accept enrollment from all Medicare-enrolled providers and suppliers

(even if a provider or supplier is of a type that the State would not otherwise enroll in the State Medicaid program), if the provider otherwise meets all other Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E.

There are three areas where this provision would have impact; listed here and discussed in further detail later in this section.

- Updating State Medicaid systems with other provider types and cost-sharing logic.
- New providers and suppliers enrolling in State Medicaid systems.
- Reducing Medicare bad debt appeals.

We are unable to estimate the change in Medicaid program costs or on Medicare bad debt payments in this analysis because states have flexibility to choose their cost-sharing payment methodology for different provider types in their Medicaid State plan, and we do not have a clear basis for assumptions about their future choices. States can choose to pay Medicare cost-sharing at the Medicare rate, which means the State pays the amount that Medicare establishes as the cost-sharing amount. States can also choose to pay Medicare cost-sharing using the Medicaid State plan rate, which means the State takes into consideration the amount that Medicare paid when determining the amount (if any) that the State will pay to bring the provider's total payment up to the Medicaid State plan rate. Usually, the Medicaid State plan rate is lower than the Medicare rate (Medicare paid amount), resulting in no additional Medicare cost-sharing payment to the provider from the State. However, if the State plan rate is higher than the Medicare rate (Medicare paid amount), the State would then pay the difference between the Medicare paid amount and the State plan rate. States can also choose to apply a lesser-of policy, in which states pay the lesser of the cost-sharing based on the Medicare rate or the State plan rate. Lastly, states can pay at a negotiated rate.

Historically, most states elect a lesser-of policy for State payment of cost-sharing for hospital claims, meaning that they pay very little, if any, Medicare cost-sharing. For example, 43 states used the lesser-of policy for cost-sharing for Medicare inpatient hospital claims in 2018. Given this, and that the states that would be impacted by this proposal are those that have not enrolled certain Medicare provider types, it seems plausible that these states would choose to elect lesser-of payment policies for these newly enrolled provider types, generally limiting new cost-sharing liability to zero. However, because states have the flexibility to set their cost-sharing methodology for newly enrolled provider types, we have not estimated costs based on those future elections. However, by properly processing claims for Medicare cost-sharing it ensures Medicare is not inappropriately paying bad debt on any cost-sharing liability the State should have paid through its State plan elections.

a. Updating State Medicaid Systems With Other Provider Types and Cost-Sharing Logic

To estimate the costs of this proposal, we note that Medicare LTCHs are an example of a Medicare-enrolled provider that is most notably not an explicit provider type in Medicaid. Therefore, we assume that 26 states will need to make systems changes to implement the proposal if finalized since this is the number of states named in the Select Specialty Hospital—*Denver, et al.* v. *Azar* case in which 77 LTCHs from 26 states appealed the denial of claims for Medicare bad debt because the LTCHs were unable to furnish a Medicaid remittance advice. While there may be other states or territories that do not enroll other provider types, such as Comprehensive Outpatient Rehabilitation Facilities (CORFs), we have less information on this circumstance and, for the purposes of this analysis, assume that the 26 states included in the LTCH litigation are the same states that may not be enrolling these other provider types. As such, we have estimated a one-time burden for 26 State and territory Medicaid programs to comply with the provider enrollment requirement as proposed. We estimate that it would take a maximum of 6 months of work (approximately 960 hours) by a computer programmer working at a Bureau of Labor Statistics (BLS) mean hourly rate of $44.53 per hour to make the necessary systems changes. Since we estimate that 26 states and territories would need to make changes, we project an aggregate burden of $1,111,469 (26 states * 960 hours of programming work * $44.53/hour) and a cost per State of approximately $42,749 (960 * $44.53 = $42,749). The cost and time attributable to this systems change will be influenced by whether the State is implementing other enrollment systems changes at the same time. Assuming the State implements this change in isolation, we estimate that this change could take 6 months. However, if a State makes this change as a part of a broader enrollment systems update, the work specific to proposal could be minimal. We note that states are likely eligible for 90/10 Federal medical assistance percentage (FMAP) for the State Medicaid Management Information System (MMIS) as set forth in 1903(a)(3)(A) of the Act.

We estimate a 6-month implementation period for these system updates. In this proposed rule, we assume there will be 17 months between when we expect to publish a final rule in August 2021, and the January 1, 2023 applicability date. The purpose of the 17-month window is to give organizations flexibility to find a 6-month period to perform updates as indicated in section X.A. of the preamble of this proposed rule. States would have the ability to choose, in consultation with CMS, when in the 17-month implementation period they want to make this change. For the purposes of this impact analysis, we estimated a uniform distribution beginning in August 2021 and ending in January 2023. As noted previously, the total cost impact over 17 months is $1,111,469, when apportioned uniformly over the 17 months, the resulting impacts are $322,326 and $789,143 for 2021 and 2022 respectively corresponding to 5 months and 12 months in 2021 and 2022, respectively. We solicit comment on Medicaid costs of systems updates related to this proposal.

b. New Providers and Suppliers Enrolling in State Medicaid Systems

Currently, there are 363 LTCHs across the United States, and our understanding is that at least half are in a Core Based Statistical Area (CBSA) in which the states currently enroll LTCHs. If half of LTCHs are able to newly enroll with their State Medicaid program, we estimate enrollment will take an average of three to six hours for an LTCH office manager, at a BLS mean hourly rate of $28.91 per hour, to complete so would cost between $86.73 and $173.46 for each LTCH (3 to 6 hours * $28.91/hr). Therefore, we estimate this will cost LTCHs between $15,611 and $31,223 ($86.73 to $173.46 * 180 LTCHs) in aggregate. We assume that, on average, it will take states a similar amount of time to review and process these enrollment applications, though we know that some applications can be adjudicated quickly through automated processes, and others will need manual review. We estimate states will need to process enrollment applications for 180 LTCHs, across 26 states, for a total costs of between $15,611 and $31,223, or $600 to $1,200 per State ($15,611 to $31,223/26 states). While this proposal may also impact other provider and supplier types, such as CORFs, we are uncertain how many of these provider types will be able to newly enroll in Medicaid as a result of this proposal. We solicit comment on the enrollment application and processing impacts related to this proposal.

c. Reducing Medicare Bad Debt Appeals

This proposed rule will not affect existing bad debt appeals. However, we believe the proposed rule may reduce the number of future bad debt appeals by ensuring certain Medicare-enrolled providers, such as LTCHs, can enroll with State Medicaid programs, receive Medicaid Remittance Advice (RA), and claim Medicare bad debt. In eliminating these appeals, the proposal would eliminate the cost for providers to pursue such appeals and subsequent litigation, as well as the costs for CMS to defend them. Therefore, we estimate provider and Medicare cost savings from avoiding future Medicare bad debt appeals. As noted previously, we are unable to estimate a reduction in Medicare bad debt payments that would result from an increase in State payment of Medicare LTCH cost-sharing because states have flexibility to choose their cost-sharing payment methodology for different provider types in their State plan, and we do not have a clear basis for assumptions about their future choices.

While we cannot predict the outcome of future appeals and litigation, the February 2021 resolution of the Select Specialty Hospital—*Denver, et al.* v. *Azar* case, which included claims from 77 LTCHs in 26 states from 2005 to 2010, helps us better understand the potential appeal-related costs avoided if we finalize this proposal.

Medicare Hospital Insurance Trust Fund Payments. After an adverse decision for CMS, the Federal government ultimately paid the plaintiffs a total of $23,649,492, which included the principle amount of $18,656,588 for the payment of bad debt claims that had been denied, plus associated

interest of $4,992,904. In determining the principle amount to be paid, it was difficult for CMS to retroactively determine State liability for cost-sharing, if any, in order to deduct that amount from the amount claimable as bad debt. If finalized, this proposal would help ensure that the amount paid for bad debt accurately reflects State liability. Additionally, by reducing the need for bad debt appeals and litigation, it would also eliminate costs associated with interest, should future cases be decided similarly to Select Specialty Hospital—*Denver, et al.* v. *Azar*.

Litigation costs. In the Specialty Hospital—*Denver, et al.* v. *Azar* case, the plaintiffs sought $1,174,000 in total costs of attorney's fees and costs incurred to litigate denied Medicare bad debt claims dating from 2005 to 2010 through the Medicare Provider Reimbursement Review Board (PRRB) and in Federal District Court. The court denied this request, so these costs were borne by the LTCHs.

The Federal government also bears significant costs to process and defend these appeals and subsequent litigation: The MAC and the Federal Specialized Service prepare the documentation to present at the PRRB; the PRRB prepares the case for the hearing and prepares and issue a decision; the CMS Attorney Advisor disseminates the PRRB decision to the appropriate parties, such as the Federal Specialized Service and CMS payment policy staff, for input on the PRRB decision and then issues a final Administrator's decision on the case; the Office of General Council prepares and files the appropriate documentation to hear the court case which may also involve components of the U.S. Department of Justice; and the Office of General Council defends the case, and if necessary, works with CMS to determine an appropriate settlement that the MAC then implements. Currently, there are at least 20 open cases before CMS for the same issue ruled on in the Select Specialty Hospital—Denver case, claims with dates of service from 2007 to 2020. We estimate the provider bad debt reimbursement in controversy across these 20 open cases to be $17,248,242. Of these 20 open cases, nine cases are under remand from the Federal District Court with a calculated potential interest amount of $2,740,794.

If this proposal is not finalized, it is likely that appeals on this issue, and their associated costs for Medicare providers and for the Federal government described previously, would continue into the future. We solicit comment on the cost and savings related to appeals resulting from this proposed policy.

In sum, we note that the estimated costs saved by providers, CMS, and other Federal agencies in avoiding ongoing Medicare bad debt appeals likely offset the maximum $31,223 in aggregate spending for providers and suppliers to enroll with State Medicaid programs, and the maximum $31,223 for states to process those applications, as well as the $1,111,469 in aggregate spending for states to update the State Medicaid systems, which will likely be eligible for 90/10 FMAP, as described previously.

11. Effects of the Proposed Organ Acquisition Payment Policy

In section X.B.2. of the preamble of this proposed rule, we are proposing to codify into the Medicare regulations some longstanding Medicare organ acquisition payment policies, with clarifications where necessary, and proposing to codify some new organ acquisition payment policies. Specifically, in section X.B.2.h. of the preamble of this proposed rule, we are proposing to revise and codify the Medicare organ counting policy to more accurately record and pay Medicare's share of organ acquisition costs. Additionally in section X.B.2.l. of the preamble of this proposed rule, we are proposing to revise and codify the policy for donor community hospital (Medicare-certified non-transplant hospitals) charges for services provided to organ procurement organizations. In section X.B.2.m. of the preamble of this proposed rule, we are also proposing to make technical corrections, clarifications, conforming changes, and redesignations in the regulations. Finally, in section X.B.3. of the preamble of this proposed rule, we are soliciting comments on the existing cap on surgeon fees for cadaveric kidney excisions.

As a result of our proposal to codify certain longstanding organ acquisition payment policies into the regulations, there would be no additional costs to the Medicare program and no increased burden placed upon transplant hospitals, OPOs or other stakeholders. Likewise, there would be no costs or savings to the Medicare program from the technical corrections, clarifications, conforming changes, or redesignations of some regulations. There would also be no costs or savings to the Medicare program from the comment solicitation related to surgeon fees.

As a result of our proposal to revise and codify the Medicare usable organ counting policy to count only organs transplanted into Medicare beneficiaries so that Medicare more accurately records and pays its share of organ acquisition costs, we estimate an annual cost savings to the Medicare trust fund of $230 million in FY 2022, $1.74 billion over 5 years, and $4.150 billion over 10 years. OACT estimated these savings on a cash basis using IPPS cost data. These savings estimates also include effects associated with the impacts to Medicare Advantage plans. These effects which are unrelated to our proposal, include the changes resulting from the 21st Century Cures Act, which requires that kidney acquisition costs for Medicare Advantage beneficiaries be paid under Fee-for-service Medicare beginning January 1, 2021, rather than under Medicare Advantage (section 17006 of Pub. L. 114–255).

As a result of our proposal to revise and codify the policy for donor community hospital charges for services provided to organ procurement organizations, we are currently unable to estimate a cost savings. Based on the Scientific Registry of Transplant Recipient data, we recognize that organs recovered from donor community hospitals comprised 62 percent of all transplanted organs in 2017 and 2018.[1529] Under the current policy donor community hospitals bill customary charges or negotiated rates and not charges reduced to cost. Because our proposal requires donor community hospitals to reduce charges to cost, we anticipate a cost savings to the Medicare trust fund.

12. Effects of the Proposed Policy Changes to the Medicare Shared Savings Program

In section X.C. of the preamble of this proposed rule, we describe our proposed changes to the Medicare Shared Savings Program (Shared Savings Program) established under section 1899 of the Act. The proposed changes are estimated to reduce program spending relative to a status quo baseline by extending the flexibility for certain ACOs to elect to ''freeze'' their participation level along the BASIC track's glide path for PY 2022. Such special flexibility—having proven popular among ACOs that chose to ''freeze'' their level of participation for PY 2021 in light of the uncertainties caused by the COVID–19 PHE, is expected to again help retain ACO participation in the program, particularly among ACOs leery of taking on downside risk, or increasing levels of downside risk, in the midst of pandemic-related uncertainty. In modeling the impacts of the proposed changes, we used ACO performance data from the 6-month performance year from July 1, 2019, through December 31, 2019, based on CY 2019, along with preliminary data from performance year 2020 to identify ACOs that would be likely to opt for this flexibility and to estimate the potential impact on program spending. We also considered the benchmark and performance information ACOs would have available when making participation decisions for PY 2022 in the context of participation decisions made by ACOs in similar positions entering PY 2021.

We estimate that the proposed flexibility would prevent between 20 to 30 ACOs that would otherwise be required to transition to performance-based risk in PY 2022 from dropping out of the Shared Savings Program. Additionally, we estimate that between 60 to 80 ACOs that would otherwise attempt the transition to performance-based risk would, out of caution, opt to stay in a one-sided model in PY 2022 (that is BASIC track Level A or B) despite the opportunity to graduate to a higher level of potential reward (under BASIC track Levels A and B, ACOs share at most 40 percent of savings, whereas BASIC track Levels C, D, and E allow for greater upside potential with a maximum sharing rate of 50 percent). The net effect of offering this flexibility is estimated to be a $90 million reduction in Federal spending, with the reduction ranging from $50 to $140 million. The estimated impact is roughly evenly split between net savings generated by ACOs that would have otherwise have terminated their participation in the program absent the flexibility and reduced shared savings payouts to ACOs that would elect to remain at the lower sharing rates in Levels A or B of the BASIC track despite the fact they would have ultimately earned—as a group—more shared savings had they transitioned to a risk arrangement in Level C, D, or E of the BASIC track. Although we estimate the impact of this proposal over the single performance year for which it would

[1529] Scientific Registry of Transplant Recipients. Request for Information. Requested on 02/08/2021.

expand certain ACOs' participation options, it is possible there could be secondary impacts over a longer time period. However, we do not believe the longer run potential effects are readily quantifiable on net. On one hand, the policy could allow certain ACOs to delay making more aggressive care delivery changes if they expect CMS to likely continue to offer risk-free participation in the program in future rulemaking, as would have been the case for two successive rules (the May 8, 2020 COVID–19 Interim Final Rule with Comment Period and this FY 2022 Medicare Hospital Inpatient Prospective Payment System proposed rule). On the other hand, the proposal could give other ACOs additional time to grow in confidence in their ability to manage the transition to risk, while at the same time finding stability in their operations after the disruption from the COVID–19 PHE. ACOs in the latter category may then find longer-term success (including driving lower net spending for the program) that might have otherwise been curtailed had the ACO been forced to decide whether or not to transition to performance-based risk for PY 2022. These two scenarios illustrate potential countervailing longer run impacts from the proposal, and while we do not attempt to estimate a net impact across the mix of such possible scenarios for ACOs impacted by this proposal, we assert that the proposal increases the chance that the program could sustain a larger mix of participants and this outcome outweighs the risk that certain ACOs might be marginally slower to make efficiency-related changes in care delivery.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

As discussed, in section III.A of the Addendum to this proposed rule, we are proposing to use claims from the March 2020 update of the FY 2019 MedPAR file and provider data from the March 2020 update of the Provider Specific File (PSF) for purposes of determining the proposed capital Federal rate for FY 2022. Consistent with these proposals, for the impact analysis presented in this section, we used data from the March 2020 update of the FY 2019 MedPAR file and the March 2020 update of the PSF that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the March 2020 update of the hospital cost report data (FYs 2017 and 2018) to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2020 update of the FY 2019 MedPAR file, we simulated payments under the capital IPPS for FY 2021 and the proposed payments for FY 2022 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the proposed capital IPPS payments in FY 2022 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this proposed rule, the proposed update to the capital Federal rate is 0.70 percent for FY 2022.
- In addition to the proposed FY 2022 update factor, the proposed FY 2022 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 1.0001, a proposed budget neutrality factor for the proposed lowest quartile hospital wage index adjustment of 0.9976, and a proposed outlier adjustment factor of 0.9467.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of the proposed changes for FY 2022 on total capital payments per case, using a universe of 3,198 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2020 update of the FY 2019 MedPAR file, the March 2020 update to the PSF, and the cost report data for FYs 2017 and 2018 from the March 2020 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2021 and estimated proposed total payments per case for FY 2022 based on the proposed FY 2022 payment policies. Column 2 shows estimates of payments per case under our model for FY 2021. Column 3 shows estimates of proposed payments per case under our model for FY 2022. Column 4 shows the proposed total percentage change in payments from FY 2021 to FY 2022. The change represented in Column 4 includes the proposed 0.70 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2022 are expected to increase as compared to capital payments per case in FY 2021. This expected increase overall is primarily due to the proposed 0.70 percent update to the capital Federal rate for FY 2022, in conjunction with estimated decrease in capital DSH payments due to the estimated increase in the number of hospitals that reclassify from urban to rural under § 412.103. We approximate that there are 78 hospitals classified as urban (for payment purposes) and receiving capital DSH payments in FY 2021, that will be classified as rural (for payment purposes) and will not receive capital DSH payments in FY 2022. Under § 412.320, in order to receive capital DSH payments a hospital must be located in an urban area for payment purposes and have 100 or more beds, and paragraph (a)(1)(iii) specifies that the geographic classification of an urban hospital that is reclassified as rural as set forth in § 412.103 is rural. In general, regional variations in estimated capital payments per case in FY 2022 as compared to capital payments per case in FY 2021 are primarily due to the proposed changes in GAFs, and are generally consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated 0.5 percent increase in capital payments per case from FY 2021 to FY 2022 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2022 as compared to FY 2021. Capital IPPS payments per case would increase by an estimated 0.5 percent for hospitals in urban areas while payments to hospitals in rural areas would increase by 1.0 percent in FY 2021 to FY 2022.

The comparisons by region show that the estimated increases in capital payments per case from FY 2021 to FY 2022 for urban areas range from a 0.2 percent increase for the West South Central region to a 1.2 percent increase for the Pacific region. We estimate a decrease for the capital payments per case from FY 2021 to FY 2022 of 0.4 percent for the Middle Atlantic urban region and 0.8 percent for the New England urban region, primarily due to changes in the GAFs and estimated decreases in DSH payments. However, all rural regions are expected to experience an increase in capital payments per case from FY 2021 to FY 2022, ranging from 0.6 percent for the West North Central rural region to 1.9 percent for the South Atlantic rural region. These regional differences are primarily due to the proposed changes in the GAFs and estimated changes in outlier and DSH payments.

All Hospital types of ownerships (Voluntary, Proprietary, and Government) are expected to experience an increase in capital payments per case from FY 2021 to FY 2022. Voluntary hospitals are expected to experience an increase in capital IPPS payments of 0.6 percent, and the projected increase in capital payments for proprietary and government hospitals is estimated to be 0.7 percent and 0.6 percent respectively.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2022. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2022, we show the proposed average capital payments per case for reclassified hospitals for FY 2022. Urban reclassified hospitals are expected to experience an increase in capital payments of 0.1 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 1.0 percent. The lower expected increase in payments for urban reclassified hospitals compared to urban nonreclassified hospitals is primarily due to estimated decreases in capital DSH payments to urban reclassified hospitals caused by the increase in the number of hospitals that reclassify from urban to rural under § 412.103. The estimated percentage increase for rural reclassified hospitals is 1.2 percent, and for rural nonreclassified hospitals, the estimated percentage increase in capital payments is 0.8 percent.

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2021 PAYMENTS COMPARED TO PROPOSED FY 2022 PAYMENTS]

	Number of hospitals	Average FY 2021 payments/ case	Proposed Average FY 2022 payments/ case	Change
All hospitals	3,198	979	984	0.5
By Geographic Location:				
Urban Hospitals	2,459	1,012	1,017	0.5
Rural areas	739	671	678	1.0
Bed Size (Urban)				
0-99 beds	633	814	822	1.0
100-199 beds	755	858	865	0.8
200-299 beds	427	935	941	0.6
300-499 beds	421	1,014	1,019	0.5
500 or more beds	223	1,215	1,219	0.3
Bed Size (Rural)				
0-49 beds	313	570	574	0.7
50-99 beds	254	625	630	0.8
100-149 beds	94	664	670	0.9
150-199 beds	39	731	739	1.1
200 or more beds	39	793	805	1.5
By Region:				
Urban by Region				
New England	112	1,101	1,092	-0.8
Middle Atlantic	304	1,121	1,116	-0.4
South Atlantic	402	886	895	1.0
East North Central	381	962	970	0.8
East South Central	144	862	867	0.6
West North Central	160	992	1,003	1.1
West South Central	364	929	931	0.2
Mountain	172	1,024	1,028	0.4
Pacific	370	1,301	1,316	1.2
Rural by Region				
New England	19	935	949	1.5
Middle Atlantic	50	647	654	1.1
South Atlantic	114	620	632	1.9
East North Central	114	677	684	1.0
East South Central	144	630	635	0.8
West North Central	89	698	702	0.6
West South Central	136	599	605	1.0
Mountain	49	762	767	0.7
Pacific	24	864	871	0.8

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2021 PAYMENTS COMPARED TO PROPOSED FY 2022 PAYMENTS]

	Number of hospitals	Average FY 2021 payments/ case	Proposed Average FY 2022 payments/ case	Change
By Payment Classification:				
Urban hospitals	1,965	989	998	0.9
Rural areas	1,233	963	964	0.1
Teaching Status:				
Non-teaching	2,034	820	828	1.0
Fewer than 100 Residents	907	933	938	0.5
100 or more Residents	257	1,356	1,359	0.2
Urban DSH:				
Non-DSH	505	902	909	0.8
100 or more beds	1,210	1,017	1,026	0.9
Less than 100 beds	350	738	745	0.9
Rural DSH:				
Sole Community (SCH/EACH)	260	687	693	0.9
Referral Center (RRC/EACH)	622	1,007	1,008	0.1
100 or more beds	34	1,027	1,003	-2.3
Less than 100 beds	217	559	565	1.1
Urban teaching and DSH:				
Both teaching and DSH	674	1,083	1,092	0.8
Teaching and no DSH	74	949	953	0.4
No teaching and DSH	886	874	883	1.0
No teaching and no DSH	331	874	882	0.9
Special Hospital Types:				
Non special status hospitals	162	872	863	-1.0
RRC/EACH	555	1,042	1,043	0.1
SCH/EACH	304	756	762	0.8
Medicare-dependent hospitals (MDH)	148	599	601	0.3
SCH, RRC and EACH	151	807	814	0.9
MDH, RRC and EACH	24	663	667	0.6
Type of Ownership:				
Voluntary	1,883	990	996	0.6
Proprietary	828	889	895	0.7
Government	487	1,034	1,040	0.6
Medicare Utilization as a Percent of Inpatient Days:				
0-25	643	1,118	1,125	0.6
25-50	2,113	969	974	0.5
50-65	366	797	798	0.1
Over 65	51	597	603	1.0
2022 Reclassifications by the Medicare Classification Review Board:				
All Reclassified Hospitals	1,048	988	991	0.3
All Nonreclassified Hospitals	2,150	970	978	0.8
Urban Hospitals Reclassified	860	1,030	1,031	0.1
Urban Nonreclassified Hospitals	1,612	994	1,004	1.0
Rural Hospitals Reclassified Full Year	304	691	699	1.2
Rural Nonreclassified Hospitals Full Year	422	639	644	0.8
All Section 401 Reclassified Hospitals	550	1,049	1,048	-0.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	662	669	1.1

J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2022. In the preamble of this proposed rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2022, and present rationales for our proposals as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 363 LTCHs included in this impact analysis. We note that, although there are currently approximately 373 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2022 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this proposed rule. Moreover, in the claims data used for this proposed rule, 3 of these 363 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.)

In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, the proposed 2.2 percent annual update to the LTCH PPS standard Federal payment rate, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2022.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019. For FY 2021 and FY 2022, we expected no site neutral payment rate cases would still be eligible for the transitional payment method since it only applies to those site neutral payment rate cases whose discharges occur during a LTCH's cost reporting period that begins before October 1, 2019. Site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1). Therefore, for purposes of this impact analysis, to estimate total LTCH PPS payments for site neutral payment rate cases in FYs 2021 and 2022 the site neutral payment rate amount was applied in full.

Based on the best available data for the 363 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2022 will increase by approximately 1.4 percent (or approximately $52 million) based on the proposed rates and factors presented in section VII. of the preamble and section V. of the Addendum to this proposed rule.

Based on the FY 2019 LTCH cases that were used for the analysis in this proposed rule, approximately 25 percent of those cases were classified as site neutral payment rate cases (that is, 25 percent of LTCH cases did not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2022 will not change significantly from the most recent historical data. Taking into account updates to the IPPS rates and other changes that will apply to the site neutral payment rate cases in FY 2022, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 3 percent (or approximately $11 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates used in calculating the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this proposed rule. We note, we estimate payments to site neutral payment rate cases in FY 2022 represent approximately 10 percent of estimated aggregate FY 2022 LTCH PPS payments.

Based on the FY 2019 LTCH cases that were used for the analysis in this proposed rule, approximately 75 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2022, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2022 will increase approximately 1.2 percent (or approximately $41 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2022 is primarily due to the proposed 2.2 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments, which is discussed later in this section.

Based on the 363 LTCHs that were represented in the FY 2019 LTCH cases that were used for the analyses in this proposed rule presented in this Appendix, we estimate that aggregate FY 2021 LTCH PPS payments will be approximately $3.771 billion, as compared to estimated aggregate proposed FY 2022 LTCH PPS payments of approximately $3.822 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $52 million. We note that the estimated $52 million increase in LTCH PPS payments in FY 2022 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2021 is $43,755.34. For FY 2022, we are proposing to establish an LTCH PPS standard Federal payment rate of $ 44,827.87 which reflects the proposed 2.2 percent annual update to the LTCH PPS standard Federal payment rate and the proposed budget neutrality factor for proposed updates to the area wage level adjustment of 1.002458 (discussed in section V.B.6. of the Addendum to this proposed rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $43,950.62. This proposed LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update of 2.2 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.1 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022, on average, for all LTCHs (Column 6). The estimated increase of 2.1 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 2.1 percent.

For FY 2022, we are proposing to update the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2018 which is the same data used for the proposed FY 2022 IPPS wage index). We also are proposing a labor-related share of 68.0 percent for FY 2022, based on the most recent available data (IGI's fourth quarter 2020 forecast) on the relative importance of the labor-related share of operating and capital costs of the 2017-based LTCH market basket. We also are proposing to apply an area wage level budget neutrality factor of 1.002458 to ensure that the proposed changes to the area wage level adjustment would not

result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2021 to FY 2022. Based on the FY 2019 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2021 high cost outlier threshold of $27,195 (as established in the FY 2021 IPPS/LTCH PPS final rule) would result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2021 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 8.8 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2021. Combined with our estimate that FY 2022 high cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2022, this will result in an estimated decrease in high cost outlier payments of approximately 0.83 percent between FY 2021 and FY 2022. We note that, in calculating these estimated high cost outlier payments, we inflated charges reported on the FY 2019 claims by the charge inflation factor proposed in section V.D.3.b. of the Addendum to this proposed rule. We also note that, in calculating these estimated high cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2022 by comparing estimated FY 2021 LTCH PPS payments to estimated FY 2022 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the best available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 1.5 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2019 data for the 19 rural LTCHs (out of 363 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Proposed Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.2. of this Appendix, we project an increase in aggregate LTCH PPS payments in FY 2022 of approximately $52 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $41 million and the projected increase in payments to site neutral payment rate cases of approximately $11 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2022 LTCH PPS payments (that is, FY 2019 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our proposed provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Proposed Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2022, it is necessary to estimate payments per discharge for FY 2021 using the rates, factors, and the policies established in the FY 2021 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2022 using the proposed rates, factors, and the policies in this FY 2022 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Proposed Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2021 and proposed FY 2022 payments on a case-by-case basis using historical LTCH claims from the FY 2019 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2019 MedPAR files. For modeling FY 2021 LTCH PPS payments, we used the FY 2021 standard Federal payment rate of $43,755.34 (or $42,899.90 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the proposed FY 2022 LTCH PPS standard Federal payment rate, we used the proposed FY 2022 standard Federal payment rate of $44,827.87 (or $43,950.62 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2021 LTCH PPS payments, we used the current FY 2021 labor-related share (68.1 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2021 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2021 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $27,195 (as reflected in the FY 2021 IPPS/LTCH PPS final rule), and the FY 2021 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2021 nonlabor-related share (31.9 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling proposed FY 2022 LTCH PPS payments, we used the proposed FY 2022 LTCH PPS labor-related share (68.0 percent), the proposed FY 2022 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website), the proposed FY 2022 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $32,680 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2022 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2022 nonlabor-related share (32.0 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2019 claims by the charge inflation factors proposed in section V.D.3.b. of the Addendum to this proposed rule. We also note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2021 to FY 2022 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2021 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated proposed FY 2022 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2021 to FY 2022 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for changes to the area wage level adjustment (that is, the updated hospital wage data and labor-related share) and the application of the proposed corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 (Column 4) to FY 2022 (Column 5) for all proposed changes.

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TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2022 (ESTIMATED FY 2021 PAYMENTS COMPARED TO ESTIMATED FY 2022 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2022 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	360	68,764	49,641	50,237	2.1	0.0	1.2
BY LOCATION:							
RURAL	19	2,998	39,667	40,246	2.2	0.1	1.5
URBAN	341	65,766	50,096	50,693	2.1	0.0	1.2
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	1,788	46,792	47,173	2.1	-0.2	0.8
OCT. 1983 - SEPT. 1993	40	8,883	55,330	56,012	2.1	0.0	1.2
OCT. 1993 - SEPT. 2002	145	28,209	48,599	49,177	2.1	0.0	1.2
AFTER OCTOBER 2002	165	29,884	49,105	49,705	2.1	0.0	1.2
BY OWNERSHIP TYPE:							
VOLUNTARY	60	8,517	52,453	52,953	2.1	0.0	1.0
PROPRIETARY	290	59,088	49,013	49,617	2.1	-0.1	1.2
GOVERNMENT	10	1,159	61,027	61,911	2.0	0.7	1.4
BY REGION:							
NEW ENGLAND	10	2,374	44,563	44,924	2.1	-0.5	0.8
MIDDLE ATLANTIC	23	5,310	57,600	57,979	2.1	-0.7	0.7
SOUTH ATLANTIC	62	13,107	48,966	49,708	2.1	0.3	1.5
EAST NORTH CENTRAL	55	10,260	48,549	49,113	2.2	0.0	1.2
EAST SOUTH CENTRAL	31	5,784	44,635	44,962	2.2	-0.5	0.7
WEST NORTH CENTRAL	22	4,152	47,110	47,704	2.2	0.5	1.3
WEST SOUTH CENTRAL	105	17,198	44,596	45,051	2.2	-0.3	1.0
MOUNTAIN	29	3,371	50,753	51,597	2.1	0.3	1.7
PACIFIC	23	7,208	65,226	66,278	2.0	0.4	1.6
BY BED SIZE:							
BEDS: 0-24	22	2,243	47,639	48,118	2.2	0.0	1.0
BEDS: 25-49	166	23,651	46,455	47,035	2.2	0.0	1.2

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d. Results

Based on the FY 2019 LTCH cases (from 363 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2022 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
BEDS: 50-74	97	19,086	50,069	50,651	2.1	-0.1	1.2
BEDS: 75-124	48	13,852	53,853	54,574	2.1	0.1	1.3
BEDS: 125-199	19	5,977	51,675	52,152	2.1	-0.3	0.9
BEDS: 200+	8	3,955	49,938	50,508	2.1	0.0	1.1

[1] Estimated FY 2022 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for changes due to the proposed changes to the area wage level adjustment under § 412.525(c) (i.e., updated hospital wage data and the proposed labor related share).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 (shown in Column 4) to FY 2022 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

standard Federal payment rate cases are projected to increase 1.2 percent, on average, for all LTCHs from FY 2021 to FY 2022 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 1.2 percent increase in LTCH PPS payments per discharge was determined by comparing estimated proposed FY 2022 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2021 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2022 by 2.2 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a proposed budget neutrality factor for proposed changes to the area wage level adjustment of 1.002458 (discussed in section V.B.6. of the Addendum to this proposed rule), based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.2 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.1 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2021 to FY 2022. We note our estimate of the changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 for all hospitals is 1.2 percent. The projected increase for urban hospitals is 1.2 percent for urban hospitals, while the projected increase for rural hospitals is 1.5 percent.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the best available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 43 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to both experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 of 1.2 percent. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are also projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022 of 1.2 percent, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 0.8 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the best available data, approximately 17 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary and proprietary LTCHs are each expected to experience an increase of 1.0 percent and 1.2 percent in payments to LTCH PPS standard Federal payment rate cases, respectively. Government owned and operated LTCHs, meanwhile, are expected to experience a 1.4 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2021 to FY 2022.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2022 are projected to increase across all census regions. LTCHs located in the Mountain region are projected to experience the largest increase at 1.7 percent. The remaining regions are projected to experience an increase in payments in the range of 0.7 to 1.6 percent. These regional variations are primarily due to the proposed changes to the area wage adjustment.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 125–199 beds will experience the lowest increase in payments for LTCH PPS standard Federal payment rate cases, 0.9 percent. LTCHs with 75–124 beds are projected to experience the largest increase in payments of 1.3 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 1.0 to 1.2 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2022 relative to FY 2021 of approximately $41 million (or approximately 1.2 percent) for the 363 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2022 relative to FY 2021 of approximately $11 million (or approximately 3 percent) for the 363 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2022 represent approximately 10 percent of total estimated FY 2022 LTCH PPS payments.) Therefore, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2022 relative to FY 2021 of approximately $52 million (or approximately 1.4 percent) for the 363 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.C. of the preamble of this proposed rule, we discuss our current and proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2023 payment determination and subsequent years.

In this proposed rule, we are proposing to: (1) Adopt the Maternal Morbidity Structural Measure beginning with a shortened reporting period from October 1 through December 31, 2021 (affecting the FY 2023 payment determination), followed by annual reporting periods (affecting the FY 2024 payment determination and subsequent years); (2) adopt the Hybrid HWM measure beginning with a one-year voluntary reporting period beginning July 1, 2022

through June 30, 2023, before requiring mandatory reporting of the measure for the reporting period that would run from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination and for subsequent years; (3) adopt the COVID–19 Vaccination Coverage Among HCP measure beginning with a shortened reporting period from October 1, 2021 through December 31, 2021 affecting the FY 2023 payment determination followed by quarterly reporting deadlines affecting the FY 2024 payment determination and subsequent years; (4) adopt two medication-related adverse event eCQMs (Hospital Harm-Severe Hypoglycemia eCQM and Hospital Harm-Severe Hyperglycemia eCQM) beginning with the CY 2023 reporting period/FY 2025 payment determination; (5) remove the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI–04) measure beginning with the FY 2023 payment determination; (6) remove two eCQMs (Anticoagulation Therapy for Atrial Fibrillation/Flutter eCQM and Discharged on Statin Medication eCQM) beginning with the FY 2026 payment determination; (7) remove the Exclusive Breast Milk Feeding (PC–05) measure beginning with the FY 2026 payment determination; (8) remove the Admit Decision Time to ED Departure Time for Admitted Patients (ED–2) measure beginning with the FY 2026 payment determination; (9) revise regulations at 42 CFR 412.140(a)(2) by replacing the term ''QualityNet Administrator'' with the term ''QualityNet security official'' and 42 CFR 412.140(e)(2)(iii) by replacing the term ''QualityNet system administrator'' with the term ''QualityNet security official''; (10) revise regulations at 42 CFR 412.140(a)(1) and 42 CFR 412.140(c)(2)(i) to remove references to ''QualityNet.org'' and replace with ''QualityNet website''; (11) require the 2015 Edition Cures Update of CEHRT for eCQMs and hybrid measures beginning with the FY 2025 payment determination; and (12) extend the effects of educational reviews for 4th quarter data such that if an error is identified during the education review process for 4th quarter data, we would use the corrected quarterly score to compute the final confidence interval used for payment determination beginning with validations affecting the FY 2024 payment determination.

As shown in summary table in section XII.B.4.k. of the preamble of this proposed rule, we estimate a total information collection burden increase for 3,300 IPPS hospitals of 2,475 hours at a cost of $101,475 annually associated with our proposed policies and updated burden estimates across a four year period from the CY 2022 reporting period/FY 2024 payment determination through the CY 2025 reporting period/FY 2027 payment determination, compared to our currently approved information collection burden estimates. Note that for the CY 2022 reporting period/FY 2024 payment determination, the total burden increase is only 1,375 hours at a cost of $56,375 due to reporting of the Hybrid HWR measure being only for two quarters versus four quarters for the CY 2023 reporting period/FY 2025 payment determination and subsequent years. We refer readers to section X.B.4 of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital IQR Program.

As described in sections IX.C.8.e. and IX.C.8.f. of the preamble of this proposed rule, we are proposing an update to certification requirements requiring the use of the 2015 Edition Cures Update for eCQMs and hybrid measures beginning with the FY 2025 payment determination. We expect this proposal to have no impact on information collection burden for the Hospital IQR Program because this policy does not require hospitals to submit new data to CMS. With respect to any costs unrelated to data submission, although this finalized proposal will require some investment in systems updates, the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs) previously finalized a requirement that hospitals use the 2015 Edition Cures Update for eCQMs (85 FR 84818 through 84825). Because all hospitals participating in the Hospital IQR Program are subsection (d) hospitals that also participate in the Medicare Promoting Interoperability Program (previously known as the Medicare and Medicaid EHR Incentive Programs), we do not anticipate any additional costs as a result of this finalized proposal. This is because the burden and costs involved in updating to the 2015 Edition Cures Update is the same regardless of whether the technology is used for eCQMs or hybrid measures. Hybrid measure data is derived from both claims and clinical EHR data, via submission of QRDA I files, and we already collect and utilize claims data and QRDA I file data for other measures in the Hospital IQR Program measure set. In other words, what hospitals need to do is not measure-dependent. Therefore, we believe that the Medicare Promoting Interoperability Program has already addressed the additional costs unrelated to data submission through their previously finalized requirements.

We also note that in sections IX.C.5. and IX.C.6 of the preamble of this proposed rule we include proposals to adopt two new eCQMs and remove four eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to those proposals, we believe that costs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining Program requirements, such as maintaining measure specifications in hospitals EHR systems for all of the eCQMs available for use in the Hospital IQR Program (83 FR 41771).

In section IX.C.5.c. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination Measure beginning with a shortened reporting period from October 1 to December 31, 2021 affecting the CY 2021 reporting period/FY 2023 payment determination followed by annual reporting beginning with the FY 2024 payment determination and subsequent years. Hospitals would submit data through the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1530]

Although the burden associated with the COVID–19 HCP Vaccination measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that it would take each IPPS subsection (d) hospital, on average, 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe an Administrative Assistant [1531] would spend between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For the shortened CY 2021 reporting period, 3 months are required. For the CY 2021 reporting period/FY 2023 payment determination, IPPS subsection (d) hospitals would incur an additional burden between 2.25 hours (0.75 hours × 3 months) and 3.75 hours (1.25 hours × 3 months) per hospital. For all 3,300 hospitals, the total burden would range from 7,425 hours (2.25 hours × 3,300 IPPS hospitals) and 12,375 hours (3.75 hours × 3,300 IPPS hospitals). Each hospital would incur an estimated cost of between $27.47 (0.75 hour × $36.62) and $45.78 (1.25 hours × $36.62) monthly and between $82.40 (2.25 hour × $36.62) and $137.33 (3.75 hours × $36.62) in total over the shortened period to complete this task. Thereafter, 12 months of data are required annually (12 months × 1 hour per month). IPPS subsection (d) hospitals would incur an additional annual burden between 9 hours (0.75 hours × 12 months) and 15 hours (1.25 hours × 12 months) per hospital and between 29,700 hours (9 hours × 3,300 IPPS hospitals) and 49,500 hours (15 hours × 3,300 IPPS hospitals) for all hospitals. Each hospital would incur an estimated cost of between $329.58 (9 hours × $36.62) and $549.30 annually (15 hours × $36.62). The estimated cost across all 3,300 IPPS hospitals would be between $271,920 ($82.40 × 3,300 IPPS hospitals) and $453,189 ($137.33 × 3,300 IPPS hospitals) for the shortened CY 2021 reporting period. The estimated cost across

[1530] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[1531] *https://www.bls.gov/oes/current/oes436013.htm.* The adjusted hourly wage rate of $36.62/hr includes an adjustment of 100 percent of the median hourly wage to account for the cost of overhead, including fringe benefits.

all 3,300 IPPS hospitals would be between $1,087,614 ($329.58 × 3,300 IPPS hospitals) and $1,812,690 ($549.30 × 3,300 IPPS hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 HCP Vaccination measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into NHSN.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of this Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

L. Effects of Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.D. of the preamble of this proposed rule, we proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section IX.D.4. of the preamble of this proposed rule, we are proposing to remove the Oncology: Plan of Care for Pain—Medical Oncology and Radiation Oncology *(NQF #0383/PCH–15)* measure beginning with the FY 2024 program year, adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the FY 2023 program year, with reporting for the FY 2023 program year from October 1 through December 31, 2021, followed by annual reporting periods beginning with the FY 2024 program year, and codify existing program policies. As stated in section XII.B.7. of the preamble of this proposed rule, we estimate the total burden reduction associated with the proposal to remove PCH–15 beginning with the FY 2024 program year to be 2.75 hours (0.25 hours × 11 PCHs) with a total cost reduction of $113 (2.75 hours × $41.00/hr). We do not estimate any changes in burden or cost in association with our other proposals for this program.

In section IX.D.5. of the preamble of this proposed rule, we are proposing to adopt a COVID–19 HCP Vaccination Measure beginning with a shortened reporting period from October 1 to December 31, 2021, affecting the FY 2023 program year followed by annual reporting beginning with the FY 2024 program year and subsequent years. PCHs would submit data through the CDC NHSN. The NHSN is a secure, internet-based system maintained by the CDC and provided free. Currently the CDC does not estimate burden for COVID–19 vaccination reporting under the CDC PRA package currently approved under OMB control number 0920–1317 because the agency has been granted a waiver under Section 321 of the National Childhood Vaccine Injury Act (NCVIA).[1532]

Although the burden associated with the COVID–19 HCP Vaccination measure is not accounted for under the CDC PRA 0920–1317 or 0920–0666, the cost and burden information is included here. We estimate that it would take each PCH, on average, approximately 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. This burden is comprised of administrative hours and wages. We believe it would take an Administrative Assistant [1533] between 45 minutes and 1 hour and 15 minutes to enter this data into NHSN. For the shortened CY 2021 reporting period (consisting of October 1, 2021 through December 31, 2021), three months would be required. For the CY 2021 reporting period/FY 2023 program year, PCHs would incur an additional burden between 2.25 hours (0.75 hours * 3 months) and 3.75 hours (1.25 hours * 3 months) per PCH. For all 11 PCHs, the total burden would range from 24.75 hours (2.25 hours * 11 hospitals) and 41.25 hours (3.75 hours * 11 hospitals). Each PCH would incur an estimated cost of between $27.47 (0.75 hour * $36.62/hr) and $45.78 (1.25 hours * 36.63/hr) monthly and between $82.40 (2.25 hours * $36.62/hr) and $137.33 (3.75 hours * $36.62/hr) in total over the shortened period to complete this task. Thereafter, 12 months of data would be required annually. Therefore, PCHs would incur an additional annual burden between 9 hours (0.75 hours/month * 12 months) and 15 hours (1.25 hours/month * 12 months) per PCH and between 99 hours (9 hours/hospital * 11 hospitals) and 165 hours (15 hours/hospital * 11 hospitals) for all PCHs. Each PCH would incur an estimated cost of between $329.58 (9 hours × $36.62/hr) and $549.30 annually (15 hours × $36.62/hr). The estimated cost across all 11 PCHs would be between $906.40 ($82.40/hospital * 11 hospitals) and $1,510.63 ($137.33/hospital * 11 hospitals) for the shortened CY 2021 reporting period. The estimated cost across all 11 PCHs would be between $3,625.38 ($329.58/hospital * 11 hospitals) and $6,042.30 ($549.30/hospital * 11 hospitals) annually thereafter. We recognize that many healthcare facilities are also reporting other COVID–19 data to HHS. We believe the benefits of reporting data on the COVID–19 HCP Vaccination measure to monitor, track, and provide transparency for the public on this important tool to combat COVID–19 outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into the NHSN.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.E.4. of the preamble of this proposed rule, we are proposing to add one measure to the Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP), and update a measure adopted in the FY 2020 IPPS/LTCH final rule. We propose to add the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure and update the denominator for the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure and also begin publicly displaying data for the quality measures Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay and the Ventilator Liberation Rate for the Post-Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP). In addition, we are proposing to publicly report measures using fewer quarters of data than previously finalized due to an exemption we granted the LTCHs under our regulations at 42 CFR 412.560(c)(4). Finally, we are seeking information on two issues: CMS' future plans to define digital quality measures (dQMs) for the LTCH QRP; the potential use of Fast Healthcare Interoperability Resources (FHIR) for dQMs within the LTCH QRP; and input on CMS continued efforts to close the health equity gap.

We note that the CDC would account for the burden associated with the COVID–19 Vaccination Coverage among HCP measure collection under OMB control number 0920–1317 (expiration January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986) (NCVIA).[1534] We refer readers to section XII.B.8, where CMS has provided an estimate of the burden and cost to LTCHs, and note that the CDC will include it in a revised information collection request for 0920–1317.

N. Effects of Proposed Requirements Regarding the Promoting Interoperability Program

In section IX.F.3.b. of the preamble of this rule, we are proposing the following changes for CY 2022 with eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) To maintain the Electronic Prescribing Objective's Query of PDMP measure as optional while increasing its available bonus from five points to 10 points for the EHR reporting period in CY 2022; (2) to modify the Provide Patients Electronic Access to Their Health Information Measure to establish a data availability requirement beginning with encounters with a date of service on or after January 1, 2016, beginning

[1532] Section 321 of the National Childhood Vaccine Injury Act (NCVIA) provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

[1533] *https://www.bls.gov/oes/current/oes436013.htm* (accessed on March 30, 2021). The hourly rate of $36.62 includes an adjustment of 100 percent of the mean hourly wage to account for the cost of overhead, including fringe benefits.

[1534] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

with the EHR reporting period in CY 2022; (3) to add a new Health Information Exchange (HIE) Bi-Directional Exchange measure as a yes/no attestation to the HIE objective as an optional alternative to the two existing measures, beginning with the EHR reporting period in CY 2022; (4) to require reporting on four of the existing Public Health and Clinical Data Exchange Objective measures (Syndromic Surveillance Reporting, Immunization Registry Reporting, Electronic Case Reporting, and Electronic Reportable Laboratory Result Reporting); (5) adding a new measure to the Protect Patient Health Information objective that requires eligible hospitals and CAHs to attest to having completed an annual assessment of the SAFER Guides, beginning with the EHR reporting period in CY 2022; (6) to remove attestation statements 2 and 3 from the Promoting Interoperability Program's prevention of information blocking requirement; and (7) to increase the minimum required score for the objectives and measures from 50 points to 60 points (out of 100 points) in order to be considered a meaningful EHR user. We are amending our regulation text as necessary to incorporate these proposed changes.

Next, in section VIII.D.3.b. of the preamble of this rule, we are proposing the following changes for CY 2023 with eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2023 for new and returning participants (eligible hospitals and CAHs); and (2) to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023, which is in alignment with the proposals under the Hospital IQR Program. We are amending our regulation text as necessary to incorporate these proposed changes.

Lastly, in section IX.F.3.b. of the preamble of this rule, we are proposing the following changes for CY 2024 with eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 180-day period in CY 2024 for new and returning participants (eligible hospitals and CAHs); and (2) to remove four eCQMs from the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2024, which is in alignment with the proposals under the Hospital IQR Program. We are amending our regulation text as necessary to incorporate these proposed changes.

For the EHR reporting period in CY 2022, the proposals summarized here are mainly extensions from or continuations of existing policies from last year's FY 2021 IPPS/LTCH PPS final rule (85 FR 58966 through 58977) and finalized proposals included in the CY 2021 PFS final rule (85 FR 84825 through 84828). However, due to the update of hospital staff professional who most likely conducts the reporting for the Medicare Promoting Interoperability Program, we have updated the Bureau of Labor Statistics wage rate, and we have updated number of registered respondents. Such changes will result in an estimated total burden cost of $879,450 for CY 2022 (a net decrease of $607,893 from CY 2021). While this rule includes proposals that would influence programmatic policies in CY 2023 and CY 2024, we do not believe they would attribute to a rise in burden hours, meaning that both prospective years would maintain the same estimated total burden cost of $879,450. We refer readers to section XXII.B. of the preamble of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare Promoting Interoperability Program.

O. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Use of FY 2020 or FY 2019 Data in the FY 2022 IPPS and LTCH PPS Ratesetting

As discussed in section II.A. of the preamble of this proposed rule, we are proposing to use the FY 2019 data for the FY 2022 IPPS and LTCH PPS ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID–19 PHE. For example, we are proposing to use the FY 2019 MedPAR claims data for purposes where we ordinarily would have used the FY 2020 MedPAR claims data, such as in our analysis of changes to MS–DRG classifications (as discussed in greater detail section II.D. of the preamble of this proposed rule). Similarly, we are proposing to use cost report data from the FY 2018 HCRIS file for purposes where we ordinarily would have used the FY 2019 HCRIS file, such as in determining the proposed FY 2022 IPPS MS–DRG (as discussed in greater detail section II.X. of the preamble of this proposed rule) and proposed FY 2022 MS–LTC–DRG relative weights (as discussed in greater detail section VI.B.of the preamble of this proposed rule). (As noted in section II.A. of the preamble of this proposed rule, the FY 2019 HCRIS data would contain many cost reports ending in FY 2020 based on each hospital's cost reporting period.) We have clearly identified throughout the preamble of this proposed rule where and how we are proposing to modify the IPPS and LTCH PPS ratesetting consistent with our proposed use of the FY 2019 data instead of the FY 2020 data we would ordinarily use if that FY 2020 data is significantly impacted by the COVID–19 PHE.

As an alternative to our proposed approach, we considered using the FY 2020 data we would ordinarily use in the FY 2022 IPPS and LTCH PPS ratesetting. For example, we considered proposing to use the FY 2020 MedPAR claims data and cost report data from the FY 2019 HCRIS file for purposes of determining the proposed FY 2022 IPPS MS–DRG relative weights and the LTCH PPS MS–LTC–DRG relative weights, as well as in determining the proposed FY 2022 budget neutrality factors and other proposed FY 2022 ratesetting.

In order to facilitate comments on this alternative approach, which we may consider finalizing for FY 2022 based on consideration of comments received, we are making available the FY 2020 MedPAR file and the FY 2019 HCRIS file that we would ordinarily have provided in conjunction with this proposed rule. We are also making available the MS–DRG and MS–LTC–DRG relative weighting factors and length of stay information calculated using the FY 2020 data we would have ordinarily used. We are making available a file with the budget neutrality and other ratesetting adjustments calculated under this alternative approach. Finally, we are making available other proposed rule supporting data files based on the use of the FY 2020 data that we ordinarily would have provided, including: The IPPS and LTCH PPS Impact Files; the AOR/BOR File; the Case Mix Index File; and, the Standardizing File.

With the exception of the FY 2020 MedPAR file, and the routine updates to the PSF file and the HCRIS file, these IPPS specific files can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*, along with the data files and information for our proposed FY 2022 IPPS ratesetting. The LTCH PPS specific files can be found on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/longtermcarehospitalpps*, along with the data files and information for our proposed FY 2022 LTCH PPS ratesetting. The FY 2020 MedPAR may be ordered in the same manner as the FY 2019 MedPAR file, and will be packaged with the updated FY 2019 MedPAR file that contains the proposed V39 MS–DRG groupings used to develop this proposed rule.

2. Market-Based MS–DRG Relative Weight Policy

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a requirement for a hospital to report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021 (85 FR 58873 through 58892); this data collection requirement is specified in 42 CFR 413.20(d)(3). We also finalized the use of this data in a new market-based methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing, beginning in FY 2024. Specifically, we finalized that we will begin using the reported median payer-specific negotiated charge by MS–DRG for MA organizations in the market-based MS–DRG relative weight methodology beginning with the relative weights calculated for FY 2024.

In section V.L. of the preamble of this proposed rule, we are proposing to repeal the requirement that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG, for cost reporting periods ending on or after January 1, 2021, as finalized in the FY 2021 IPPS/LTCH PPS final rule. We are also proposing to repeal the market-based MS–DRG relative weight methodology adopted effective for FY 2024,

as finalized in the FY 2021 IPPS/LTCH PPS final rule. We also note that we are soliciting comment on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) ratesetting. We are also considering an alternative to our proposal, to instead maintain the requirement that hospitals report the median payer-specific negotiated charge for MA organizations on the Medicare cost report, but delay the implementation of the market-based MS–DRG relative weight methodology from FY 2024 to a later date. Under this alternative to delay the implementation of the market-based MS–DRG relative weight methodology, we would maintain the market-based MS–DRG relative weight data collection policy, as finalized in the FY 2021 IPPS/LTCH PPS final rule, and would require that hospitals follow the steps outlined in the frequently asked questions document published on January 15, 2021 that provides examples for how hospitals would calculate the median payer-specific negotiated charge so that the market-based data is comparable and consistent across different negotiation tactics used by hospitals and MA organizations. We refer readers to the frequently asked questions for more information: *https://www.cms.gov/files/document/frequently-asked-questions-faqs-market-based-ms-drg-relative-weight-data-collection-and-change.pdf*.

We are inviting public comments on our proposal, as explained in section V.L. of the preamble to this proposed rule, to repeal both the market-based data collection requirement and the market-based relative weight methodology, and also on the alternative to maintain the market-based data collection requirement but delay the adoption of the market-based MS–DRG relative weight methodology to a date after FY 2024.

If we were to finalize a delay in the implementation of the market-based MS–DRG relative weight methodology, we would remain open to adjusting the methodology, as finalized in the FY 2021 IPPS/LTCH PPS final rule, through future rulemaking, prior to the new effective date. Should we finalize a delay in the effective date of the market-based MS–DRG relative weight methodology, we would conduct further analysis based on the median payer-specific negotiated charge data received on the Medicare cost report, and provide an opportunity for public comment on that analysis, prior to the new effective date for the market-based MS–DRG relative weight methodology.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $2.507 billion in FY 2022, including operating, capital, and new technology changes, as well as increased GME payments as a result of section 131 of the Consolidated Appropriations Act of 2021 and increased payments as a result of the imputed floor provision in section 9831 of the American Rescue Plan Act of 2021, as modeled for this proposed rule. The estimated change in operating payments is approximately $2.157 billion (discussed in section I.G. and I.H. of this Appendix). The estimated change in capital payments is approximately $0.048 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately $0.82 billion as discussed in section I.H. of this Appendix. The change in new technology add-on payments reflects the net impact of new and continuing new technology add-on payments. The estimated increase in payments as a result of our proposed implementation of section 9831 of the American Rescue Plan Act of 2021 (discussed in section III.G.2. of this proposed rule) is $0.191 billion. The estimated FY 2022 payments as a result of our proposed implementation of section 131 of the Consolidated Appropriations Act of 2021 (discussed in section V.K.2.a. of this proposed rule) is $0.030 billion. Total may differ from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 0.5 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there would be a $48 million increase in capital payments in FY 2022 compared to FY 2021.

The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2022. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2022. Accordingly, based on the best available data for the 363 LTCHs in our database, we estimate that overall FY 2022 LTCH PPS payments will increase approximately $52 million relative to FY 2021 primarily due to the proposal annual update to the LTCH PPS standard Federal rate.

Q. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For those reasons, and consistent with our approach in previous rulemakings (83 FR 41777, 84 FR 42697 and 85 FR 32460), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcome any public comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. Therefore, for the purposes of our estimate, and consistent with our approach in previous rulemakings (83 FR 41777, 84 FR 42697 and 85 FR 32460), we assume that each reviewer read approximately 50 percent of the proposed rule. We welcome public comments on this assumption.

We have used the number of timely pieces of correspondence on the FY 2021 IPPS/LTCH proposed rule as our estimate for the number of reviewers of this proposed rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $110.74 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 26.42 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $2,926 (26.42 hours × $110.74). Therefore, we estimate that the total cost of reviewing this proposed rule is $2,492,858 ($2,926 × 852 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies proposed in this proposed rule are estimated at $2.507 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2021 TO FY 2022

Category	Transfers
Annualized Monetized Transfers	$2.507 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2022 relative to FY 2021 of approximately $52 million based on the data for 363 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at: *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the changes to the LTCH PPS. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 363 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $52 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2021 LTCH PPS TO THE FY 2022 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$52 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at: *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this proposed rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the provisions of this proposed rule relating to IPPS hospitals will have an economically significant impact on small entities as explained in this Appendix. For example, the majority of the 3,198 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2022,'' on average are expected to see increases in the range of 3 percent, primarily due to the proposed hospital rate update, as discussed in section I.G. of this Appendix. On average, the proposed rate update for these hospitals is estimated to be 2.8 percent.

The majority of the 360 LTCH PPS hospitals included in the impact analysis shown in ''Table IV. Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Payment Rate Cases for FY 2022 (Estimated FY 2022 Payments Compared to Estimated FY 2021 Payments)'' on average are expected to see increases in the range of 1 percent, primarily due to the proposed 2.2 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments, as discussed in section I.J. of this Appendix.

This proposed rule contains a range of proposed policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this Appendix and throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. We are soliciting public comments on our estimates and analysis of the impact of our proposals on small entities. Public comments that we receive and our responses will be presented in the final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds (313 hospitals) and 50–99 beds (254 hospitals) are expected to experience an increase in payments from FY 2021 to FY 2022 of 4.0 percent and 2.6 percent, respectively, primarily driven by the proposed hospital rate update, as discussed in section I.G of this Appendix. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.

All rural LTCHs (19 hospitals) shown in Table IV. in section I.J. of this Appendix have less than 100 beds. These hospitals are expected to experience an increase in

payments from FY 2021 to FY 2022 of 1.5 percent, primarily due to the proposed 2.2 percent annual update to the LTCH PPS standard Federal payment rate for FY 2022 and the projected 0.8 percent decrease in high cost outlier payments, as discussed in section I.J. of this Appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold level is approximately $158 million. This proposed rule would not mandate any requirements that meet the threshold for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this proposed rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act.

As discussed in section V.E.4. of the preamble of this proposed rule, we continue to seek comment on the methodology for determining uncompensated care payments to IHS and Tribal hospitals. Consistent with Executive Order 13175, we also continue to engage in consultation with Tribal officials on this issue. We intend to use input received from these consultations with Tribal officials, as well as the comments on this proposed rule, to inform future rulemaking.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2022, consistent with our approach for FY 2021, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2022

A. Proposed FY 2022 Inpatient Hospital Update

As discussed in section IV.A. of the preamble to this proposed rule, for FY 2022, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets effective beginning in FY 2018. In this proposed rule, we are proposing to replace the 2014-based IPPS operating and capital market baskets with the rebased and revised proposed 2018-based IPPS operating and capital market baskets beginning in FY 2022.

In this FY 2022 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2022 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2020, which is estimated to be 2.5 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this FY 2022 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2020 forecast, we are proposing a MFP adjustment of 0.2 percentage point for FY 2022. We are also proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and MFP adjustment for the FY 2022 IPPS/LTCH PPS final rule.

Therefore, based on IGI's fourth quarter 2020 forecast of the proposed 2018-based IPPS market basket and the MFP adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the following table.

FY 2022	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	2.5	2.5	2.5	2.5
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.625	-0.625
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.875	0	-1.875
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.3**	**0.425**	**1.675**	**-0.2**

B. Proposed Update for SCHs and MDHs for FY 2022

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2022 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2022 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.A.1. of the preamble of this proposed rule.

In addition, as discussed in section IV.A.2. of the preamble of this proposed rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

Based on IGI's fourth quarter 2020 forecast of the proposed 2018 based IPPS market basket update with historical data through third quarter 2020, for this FY 2022 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we are proposing a market basket update of 2.5 percent and an MFP adjustment of 0.2 percent. Therefore, for FY 2022, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we are proposing the following applicable percentage increases to the standardized amount for FY 2022 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the FY 2022 operating standardized amount of 2.3 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent less an adjustment of 0.2 percentage point for the proposed MFP adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 1.675 percent (that is, the FY 2022 estimate of the proposed market basket rate-of-increase of 2.5 percent, less an adjustment of 0.625 percentage point (the proposed market basket rate of-increase of 2.5 percent × 0.75)/3) for failure to be a meaningful EHR user, less an adjustment of 0.2 percentage point for the proposed MFP adjustment.

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the MFP adjustment for the FY 2022 IPPS/LTCH PPS final rule.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2022

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use

section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, we are proposing to use the percentage increase in the proposed 2018-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2022 and subsequent fiscal years. Accordingly, for FY 2022, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2022 percentage increase in the proposed 2018-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2022 is 2.5 percent. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2022 market basket update and the MFP adjustment for the FY 2022 IPPS/LTCH PPS final rule.

E. Proposed Update for LTCHs for FY 2022

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2022 by 2.2 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the MFP adjustment). Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.022 in determining the LTCH PPS standard Federal rate for FY 2022. For LTCHs that fail to submit quality data for FY 2022, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.2 percent (that is, the proposed annual update for FY 2022 of 2.2 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.0020 in determining the LTCH PPS standard Federal rate for FY 2022. (We note that, as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the LTCH PPS standard Federal payment rate of 2.2 percent for FY 2022 does not reflect any budget neutrality factors).

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update of 2.0 percent. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 2.5 percent.

For FY 2022, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.2 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2022, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.2 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2021 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by 2.0 percent with the difference between this and the update amount specified in current law to be used to increase payments under MedPAC's Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' MedPAC initially recommended in March 2019 a redesign of the current hospital quality payment programs. MedPAC stated that together, these recommendations, paired with the recommendation to eliminate the current hospital quality program incentives, would increase hospital payments by increasing the base payment rate and by increasing the average rewards hospitals receive under MedPAC's Medicare HVIP. We refer readers to the March 2021 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 2.0 percent, with the remainder of the applicable percentage increase specified in current law to be used to fund its recommended Medicare HVIP, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2022 applicable percentage increase. Therefore, consistent with the statute, we are proposing an applicable percentage increase for FY 2022 of 2.3 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. Furthermore, we continue to appreciate MedPAC's recommendation concerning a new HVIP. We agree that continual improvement motivated by quality programs is an important incentive of the IPPS.

We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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