DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 409, 424, 484, 488, 489, and 498

[CMS–1747–P]

RIN 0938–AU37

Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-Term Care Hospital Quality Reporting Program Requirements

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth routine updates to the home health and home infusion therapy services payment rates for calendar year (CY) 2022 in accordance with existing statutory and regulatory requirements. This rule also provides monitoring and analysis of the Patient-Driven Groupings Model (PDGM); solicits comments on a methodology for determining the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments as result of the change in the unit of payment to 30 days and the implementation of the PDGM case-mix adjustment methodology; and proposes to recalibrate the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the low utilization payment adjustment (LUPA) thresholds for CY 2022. Additionally, this rulemaking proposes to utilize the physical therapy LUPA add-on factor to establish the occupational therapy add-on factor for the LUPA add-on payment amounts; and make conforming regulations text changes to reflect that allowed practitioners are able to establish and review the plan of care.

This rulemaking also proposes changes to the Home Health Quality Reporting Program (QRP) to remove one measure, remove two claims-based measures and replace them with one claims-based measure, publicly report two measures, propose a modification to the effective date for the reporting of the Transfer of Health to Provider-Post Acute Care and Transfer of Health to Patient-Post Acute Care (TOH) measures and Standardized Patient Assessment Data Elements and requests information on two topics: Advancing to digital quality measurement through the use of Fast Healthcare Interoperability Resources and our efforts surrounding closing the health equity gap. It also proposes modifications to the effective date for the reporting of TOH measures and certain Standardized Patient Assessment Data Elements. Additionally, this proposed rule requests information on two topics: Advancing to digital quality measurement through the use of Fast Healthcare Interoperability Resources and our efforts surrounding closing the health equity gap. It also proposes modifications to the effective date for the reporting of TOH measures and certain Standardized Patient Assessment Data Elements in the Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP. In addition, this proposed rule would incorporate into regulation certain Medicare provider and supplier enrollment policies.

In addition, this rulemaking proposes to make permanent selected regulatory blanket waivers related to home health aide supervision that were issued to Medicare participating home health agencies during the COVID–19 public health emergency (PHE), and would update the home health conditions of participation to implement Division CC, section 115 of the Consolidated Appropriations Act, 2021 (CAA 2021) regarding occupational therapists completing the initial and comprehensive assessments reflect these changes.

This proposed rule also would expand the Home Health Value-Based Purchasing (HHVBP) Model, beginning January 1, 2022, to the 50 States, territories, and District of Columbia. This rulemaking also proposes to end the original HHVBP Model one year early for the home health agencies (HHAs) in the nine original Model States, such that CY 2020 performance data would not be used to calculate a payment adjustment for CY 2022 under the original Model.

Additionally, this proposed rule establishes survey and enforcement requirements for hospice programs as set forth in Division CC, section 407, of the CAA 2021.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 27, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1747–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 submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

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–1747–P, P.O. Box 8013, Baltimore, MD 21244–8013.

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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1747–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–5229, for home health and home infusion therapy payment inquiries. For general information about home infusion payment, send your inquiry via email to *HomeInfusionPolicy@cms.hhs.gov.*

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to *HomeHealthPolicy@cms.hhs.gov.*

For more information about the Home Health Value-Based Purchasing Model, send your inquiry via email to *HHVBPquestions@cms.hhs.gov.*

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to *HHQRPquestions@cms.hhs.gov.*

For information about the home health conditions of participation, contact Mary Rossi-Coajou at: *mary.rossicoajou@cms.hhs.gov,* James Cowher at *james.cower@cms.hhs.gov,* or Jeannine Cramer at *Jeannine.cramer@cms.hhs.gov.*

For provider and supplier enrollment process inquiries: Frank Whelan, (410) 786–1302.

For information about the survey and enforcement requirements for hospice programs, send your inquiry via email to *QSOG_Hospice@cms.hhs.gov.*

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.

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Regulations Text

I. Executive Summary

A. Purpose

1. Home Health Prospective Payment System (HH PPS)

This proposed rule provides preliminary monitoring analysis of the implementation of the PDGM, discusses the change in the unit of payment to 30 days and the implementation of the PDGM case-mix adjustment methodology on estimated aggregate expenditures under the HH PPS, and includes a comment solicitation on the methodology for determining the difference between assumed versus actual behavior change on estimated aggregate expenditures for home health payments. This proposed rule would update the payment rates for HHAs for CY 2022, as required under section 1895(b) of the Social Security Act (the Act). This rule also proposes to maintain the CY 2021 LUPA thresholds for CY 2022. However, the rule also proposes to recalibrate the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2022. This proposed rule would update the CY 2022 fixed-dollar loss ratio (FDL) for outlier payments (outlier payments as a percentage of estimated total payments are not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act). Finally, this rule proposes to use the physical therapy (PT) add-on factor to establish the occupational therapy (OT) LUPA add-on factor and proposes conforming regulations text changes at § 409.43, ensuring the regulations reflect that allowed practitioners, in addition to physicians, may establish and periodically review the home health plan of care.

2. Home Health Value Based Purchasing (HHVBP) Model

In this proposed rule, we would expand the Home Health Value-Based Purchasing (HHVBP) Model to all Medicare-certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022 with CY 2022 as the first performance year and CY 2024 as the first payment year, based on HHA performance in CY 2022. This rule also proposes to end the original HHVBP Model 1 year early for the HHAs in the nine original Model States, such that CY 2020 performance data would not be used to calculate a payment adjustment for CY 2022.

3. Home Health (HH) Quality Reporting Program (HH QRP), Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP

This proposed rule would update the HH QRP by removing an OASIS-based measure, the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure, from the HH QRP under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This proposed rule also proposes to replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable measure and proposes to publicly report the Percent of Residents Experiencing One or More Major Falls with Injury measure and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) measure beginning in April 2022. Finally, this proposed rule proposes revisions for certain HHA QRP reporting requirements. This proposed rule would also revise similar compliance dates for certain IRF QRP and LTCH QRP requirements.

4. Proposed Changes to the Home Health Conditions of Participation

In this rule, we propose to make permanent selected regulatory blanket waivers related to home health aide

supervision that were issued to Medicare participating home health agencies during the COVID–19 PHE. In addition, Division CC, section 115 of CAA 2021 requires CMS to permit an occupational therapist to conduct a home health initial assessment visit and complete a comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care, with either physical therapy or speech therapy, and when skilled nursing services are *not* initially in the plan of care.

We are proposing changes to the home health aide supervision requirements at § 484.80(h)(1) and § 484.80(h)(2) and conforming regulation text changes at § 484.55(a)(2) and (b)(3), respectively, to allow occupational therapists to complete the initial and comprehensive assessments for patients in accordance with changes in the law.

5. Medicare Coverage of Home Infusion Therapy

This proposed rule includes updates to the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act.

6. Provider and Supplier Enrollment Processes

In section VI. of this proposed rule, we address a number of provisions regarding Medicare provider and supplier enrollment. Most of these provisions involve the incorporation into 42 CFR part 424, subpart P of certain subregulatory policies. These are addressed in section VI.B. of this proposed rule and include, for example, policies related to: (1) The effective date of billing privileges for certain provider and supplier types and certain provider enrollment transactions; and (2) the deactivation of a provider or supplier's billing privileges.

In addition, we propose in section VI.C. of this proposed rule two regulatory clarifications related to HHA changes of ownership and HHA capitalization requirements.

7. Survey and Enforcement Requirements for Hospice Programs

In this proposed rule, CMS seeks to increase and improve transparency, oversight, and enforcement for hospice programs in addition to implementing the provisions of Division CC, section 407(b) of CAA 2021. CMS continues to review and revise our health and safety requirements and survey processes to ensure that they are effective in driving quality of care for hospice programs.

B. Summary of the Provisions of This Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this rule, we provide data analyses on PDGM utilization since implementation of the new payment system in CY 2020. We describe a methodology for determining budget neutrality for CY 2020 and solicit comments on the difference between assumed versus actual behavior change on estimated aggregate expenditures.

In section II.B.3. of this rule, we propose to recalibrate the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while proposing to maintain the CY 2021 LUPA thresholds for CY 2022. The PDGM relies on clinical characteristics and other patient information to place patients into meaningful payment categories and eliminates the use of therapy service thresholds, as required by section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the Bipartisan Budget Act of 2018 (BBA of 2018).

In section II.B.4. of this rule, we propose to update the home health wage index, the CY 2022 national, standardized 30-day period payment amounts and the CY 2022 national per-visit payment amounts by the home health payment update percentage. The home health payment update percentage for CY 2022 is estimated to be 1.8 percent. Additionally, this proposed rule proposes to update the FDL ratio to 0.41 for CY 2022.

In section II.B.4.(c).(5). of this proposed rule, we discuss the regulations under Division CC, section 115 of CAA 2021 that revised §§ 484.55(a)(2) and 484.55(b)(3) to allow occupational therapists (OTs) to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care. We propose to utilize the physical therapy (PT) LUPA add-on factor to establish the OT add-on factor for the LUPA add-on payment amounts.

In section II.B.6. of this proposed rule, we are proposing conforming regulations text changes at § 409.43 to reflect that allowed practitioners, in addition to physicians, may establish and periodically review the home health plan of care in accordance with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020).

2. Home Health Value Based Purchasing (HHVBP) Model

In section III.A. of this proposed rule, we are proposing to expand the HHVBP Model to all Medicare-certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022 with CY 2022 as the first performance year and CY 2024 as the first payment year, with a proposed maximum payment adjustment, upward or downward, of 5-percent. We propose that the expanded Model would generally use benchmarks, achievement thresholds, and improvement thresholds based on CY 2019 data to assess achievement or improvement of HHA performance on applicable quality measures and that HHAs would compete nationally in their applicable size cohort, smaller-volume HHAs or larger-volume HHAs, as defined by the number of complete unique beneficiary episodes for each HHA in the year prior to the performance year. All HHAs certified to participate in the Medicare program prior to January 1, 2021 would be required to participate and eligible to receive an annual Total Performance Score based on their CY 2022 performance. We propose the applicable measure set for the expanded Model, as well as policies related to the removal, modification, and suspension of quality measures, and the addition of new measures and the form, manner and timing of the OASIS-based, HHCAHPS survey-based, and claims-based measures submission in the proposed applicable measure set beginning CY 2022 and subsequent years. We also include proposals for an appeals process, an extraordinary circumstances exception policy, and public reporting of annual performance data under the expanded Model.

In section III.B. of this proposed rule, we propose to end the original HHVBP Model one year early. We propose that we would not use CY 2020 performance data for the HHAs in the nine original Model States to apply payment adjustments for the CY 2022 payment year. We also propose that we would not publicly report CY 2020 (performance year 5) annual performance data under the original HHVBP Model.

3. HH QRP

In section IV.C. of this proposed rule, we propose updates to the HH QRP including: The removal of one OASIS-based measure, replacement of two claims-based measures with one claims-based quality measure; public reporting of two measures; revising the compliance date for certain reporting

requirements for certain HH QRP reporting requirements and requests for information regarding digital quality measures and health equity.

4. Proposed Changes to the Home Health Conditions of Participation

In section IV.D. of this rule, we propose to make permanent selected regulatory blanket waivers related to home health aide supervision that were issued to Medicare participating home health agencies during the COVID–19 PHE. In addition, Division CC, section 115 of CAA 2021 requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy and skilled nursing services are not initially on the plan of care. We are proposing changes to the home health aide supervision requirements at § 484.80(h)(1) and (h)(2) and we are proposing conforming regulation text changes at § 484.55(a)(2) and (b)(3), respectively to allow occupational therapists completing the initial and comprehensive assessments for patients

5. Medicare Coverage of Home Infusion Therapy

In section V.A.1. of this proposed rule, we discuss the home infusion therapy services payment categories, as finalized in the CYs 2019 and 2020 HH PPS final rules with comment period (83 FR 56406, 84 FR 60611). In section V.A.2. of this proposed rule, we discuss the home infusion therapy services payment adjustments including a proposal to update the GAFs used for wage adjustment and a proposal to maintain the percentages finalized for the initial and subsequent visit policy. In section V.A.3. of this proposed rule, we discuss updates to the home infusion therapy services payment rates for CY 2022, as required by section 1834(u) of the Act.

6. Provider and Supplier Enrollment Processes

In section VI. of this proposed rule, we address a number of provisions regarding Medicare provider and supplier enrollment. Most of these provisions involve the incorporation into 42 CFR part 424, subpart P of certain subregulatory policies. These are addressed in section VI.B. of this proposed rule and include, for example, policies related to: (1) The effective date of billing privileges for certain provider and supplier types and certain provider enrollment transactions; and (2) the deactivation of a provider or supplier's billing privileges.

In addition, we propose in section VI.C. of this proposed rule two regulatory clarifications related to HHA changes of ownership and HHA capitalization requirements.

7. Survey and Enforcement Requirements for Hospice Programs

In section VII. of this proposed rule, there are a number of provisions related to Division CC, section 407 of CAA 2021. These proposed provisions enhance the hospice program survey process by requiring the use of multidisciplinary survey teams, prohibiting surveyor conflicts of interest, expanding CMS-based surveyor training to accrediting organizations (AOs), and requiring AOs with CMS-approved hospice programs to begin use of the Form CMS–2567. Additionally, the proposed provisions establish a hospice program complaint hotline. Finally, the proposed provisions create a Special Focus Program (SFP) for poor-performing hospice programs and the authority for imposing enforcement remedies for noncompliant hospice programs including the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies.

Section 1865(a) of the Act provides that CMS may recognize and approve national AO Medicare accreditation programs which demonstrate that their health and safety standards and survey and oversight processes meet or exceed those used by CMS to determine compliance with applicable requirements. The CAA 2021 provisions expanding requirements for AOs will apply to AOs that accredit and ''deem'' hospice programs, and currently there are three such AOs: Accreditation Commission for Health Care (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). Half of all the Medicare-certified hospices have been deemed by these AOs.

We describe and solicit comments on all aspects of these proposed survey and enforcement provisions for hospice programs.

8. Inpatient Rehabilitation Facility Quality Reporting Program

In section IX.A. of this proposed rule, we propose to modify the compliance date for certain reporting requirements in the IRF QRP.

9. Long Term Care Hospital Quality Reporting Program

In section IX.B. of this proposed rule, we propose to modify the compliance date for certain reporting requirements in the -LTCH QRP.

C. Summary of Costs, Transfers, and Benefits

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TABLE 1: SUMMARY OF COSTS, TRANSFERS, AND BENEFITS

Provision Description	Costs and Cost Savings	Transfers	Benefits
CY 2022 HH PPS Payment Rate Update		The overall economic impact of the HH PPS payment rate update is an estimated $310 million (1.7 percent) in increased payments to HHAs in CY 2022.	To ensure home health payments are consistent with statutory payment authority for CY 2022.
HHVBP		The overall economic impact of the HHVBP Model for CYs 2022 through 2026 is an estimated $3.154 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.	
HH QRP	The total savings beginning in CY 2023 is an estimated $2,762,277 based upon the removal of one OASIS-based measure, item M2016.		
Changes to the Home Health Conditions of Participation	We do not anticipate any costs or cost savings associated with our proposed Conditions of Participation provisions.		
Medicare Coverage of Home Infusion Therapy		The overall economic impact of updating the payment rates for home infusion therapy services is expected to be minimal, based on the percentage increase in the CPI-U reduced by the productivity adjustment for CY 2022. The CPI-U for June 2021 was not yet available at the time of this proposed rule.	To ensure that payment for home infusion therapy services are consistent with statutory authority for CY 2022.
Provider and Supplier Enrollment Processes	We do not anticipate any costs or cost savings associated with our proposed Medicare provider and supplier enrollment provisions.	The overall impact of our proposed provider enrollment provisions would be a transfer of $54,145,000 from providers/suppliers to the Federal government. This would result from our proposed provision prohibiting payment for services and items furnished by a deactivated provider or supplier.	
Survey and Enforcement Requirements for Hospice Programs	We estimate that the proposal that we present in the preamble of this proposed rule to implement Division CC, section 407 of CAA 2021 would result in an estimated cost of approximately $5.5 million from FY 2021 through FY 2022.	We do not anticipate any transfers associated with our proposed Medicare survey and enforcement requirements for hospice programs.	To ensure a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public.

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II. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. Statutory Background

Section 1895(b)(1) of the Act requires the Secretary to establish a Home Health Prospective Payment System (HH PPS) for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act required that, in defining a prospective payment amount, the Secretary will consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

In accordance with the statute, as amended by the Balanced Budget Act of 1997 (BBA), (Pub. L. 105–33, enacted August 5, 1997) we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. Section 4603(a) of the BBA allowed the Secretary to consider an appropriate unit of service and at such time, a 60-day unit of payment was established. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA) (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113,

enacted November 29, 1999). For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring home health agencies (HHAs) to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable payment percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

Section 51001(a)(1)(B) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1895(b) of the Act to require a change to the home health unit of payment to 30-day periods beginning January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service furnished that end during the 12-month period beginning January 1, 2020, in a budget neutral manner, such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary to annually determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. Finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

2. Current System for Payment of Home Health Services Beginning in CY 2020 and Subsequent Years

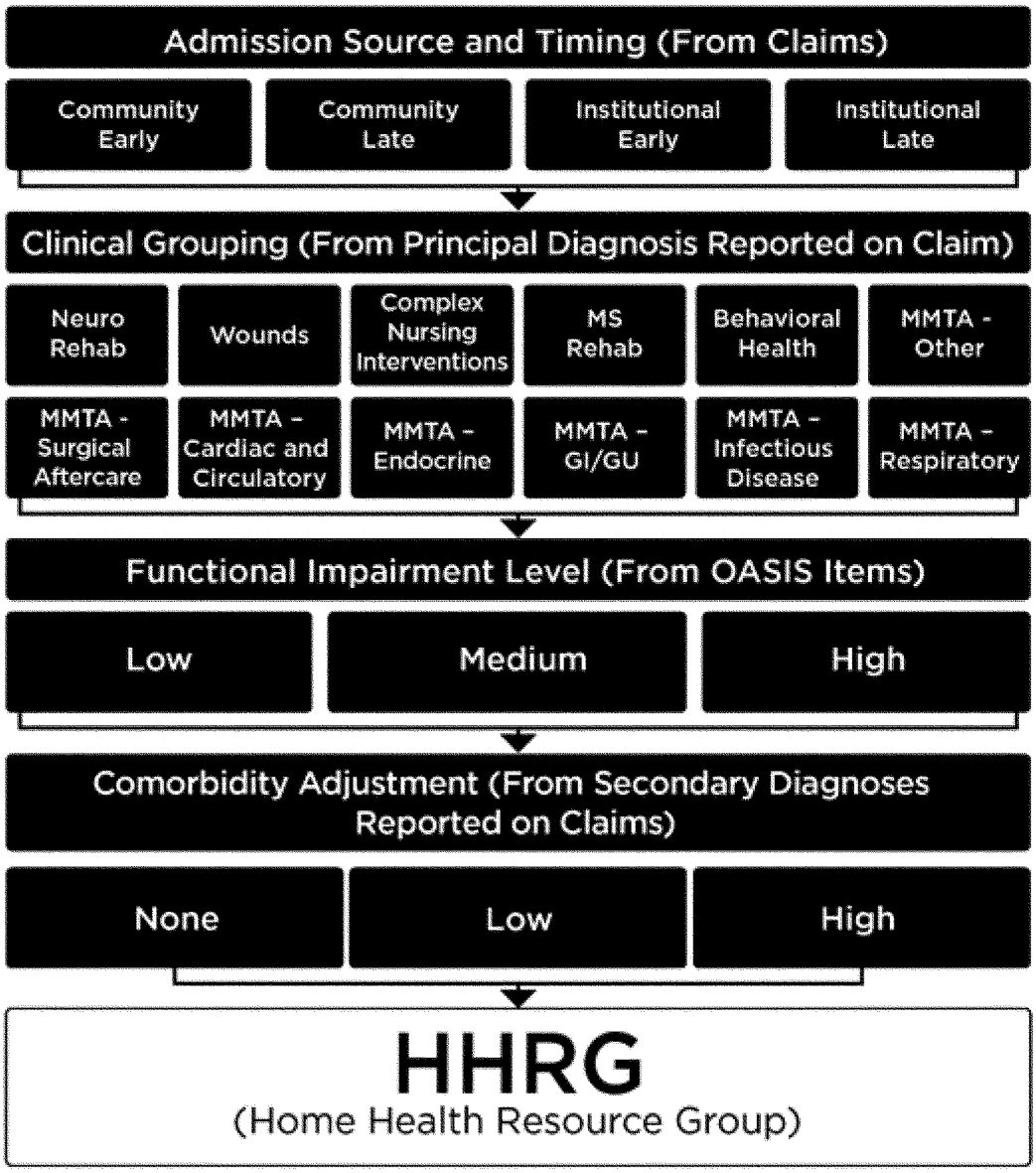
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period payment rate includes payment for the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is now also part of the national, standardized 30-day period rate. Durable medical equipment provided as a home health service, as defined in section 1861(m) of the Act, is paid the fee schedule amount or is paid through the competitive bidding program and such payment is not included in the national, standardized 30-day period payment amount.

To better align payment with patient care needs and to better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE2000 available at *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2020-transmittals/se20005*. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) assessment instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in Figure 1. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the

services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment (PEP). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories (admission source, timing clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. A detailed description of each of the case-mix variables under the PDGM have been described previously, and we refer readers to the CY 2021 HH PPS final rule (85 FR 70303 through 70305).

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



B. Proposed Provisions for Payment Under the HH PPS

1. Monitoring the Effects of the Implementation of PDGM

a. Background

The PDGM made several changes to the HH PPS, including replacing 60-day episodes of care with 30-day periods of care, removing therapy volume from directly determining payment, and developing 432 case-mix adjusted payment groups in place of the previous 153 groups. In the CY 2020 HH PPS final rule with comment period (84 FR 60513), we stated that continued monitoring is needed to understand how the PDGM, including the variables that determine the case-mix weights, affects the provision of home health care in order to inform any future refinements, if needed.

CMS recognizes it takes time for HHAs to operationalize and adjust to a new payment system. We believe these adjustments are still occurring and HHAs are still adjusting to the new payment system given that these changes are the most significant changes to the HH PPS since its inception in

2000. Additionally, the COVID–19 PHE was declared on January 31, 2020 and was retroactive to January 27, 2020.[1] Therefore, any emerging trends may or may not be temporary, permanent, or unrelated to the implementation of the PDGM. Nevertheless, we understand stakeholders want to learn about how home health utilization patterns may have changed under the PDGM, so we are providing preliminary information in this proposed rule.

b. Claims Data Overview Used in PDGM Monitoring

We believe using actual claims data, whenever possible, will provide the most comprehensive and complete evaluation of changes before and after implementation of the PDGM. Prior to the PDGM, HHAs were paid a case-mix adjusted payment for 60-day episodes of care using one of the 153 HHRGs with various therapy utilization thresholds. Under the PDGM, HHAs are paid a case-mix adjusted payment for 30-day periods of care using one of the 432 HHRGs that do not include therapy thresholds. For our analysis, we used the analytic file described in the CY 2020 HH PPS final rule with comment period (84 FR 60512) and applied the three behavioral assumptions to only half of the 30-day periods of care (randomly selected). That is, we used the CY 2018 home health data to divide one 60-day episode of care into two simulated 30-day periods of care that were used to set payment rates in the CY 2020 HH PPS final rule with comment period (84 FR 60518). We also used the analytic file described in the CY 2021 HH PPS final rule (85 FR 70298) and applied the three behavioral assumptions to only half of the 30-day periods of care (randomly selected). That is, we used the CY 2019 home health data to divide one 60-day episode of care into two simulated 30-day periods of care that we used to for routine rate-setting updates and changes for CY 2021. The simulated data in these analytical files represent pre-PDGM utilization. We refer readers to the CY 2019 HH PPS proposed rule (83 FR 32382 through 32388) for a detailed description of how these analytical files were created. Finally, we used CY 2020 claims data as of March 30, 2021 to analyze utilization changes post-implementation of the PDGM and 30-day unit of payment.

c. Routine PDGM Monitoring

As noted previously, section 1895(b)(3)(D) of the Act requires CMS to annually determine the impact of assumed versus actual behavior changes on aggregate expenditures under the HH PPS for CYs 2020 through 2026. Analyses for routine monitoring may include, but would not be limited to, analyzing: Overall total 30-day periods of care and average periods of care per HHA user; the distribution of visits in a 30-day period of care; the percentage of periods that receive the low-utilization payment adjustment (LUPA); the percentage of 30-day periods of care by clinical group, comorbidity adjustment, admission source, timing, and functional impairment level; and the proportion of 30-day periods of care with and without any therapy visits. As a reminder, the beginning of CY 2020 included ongoing 60-day episodes of care that began in CY 2019 and ended in CY 2020. Depending on the length of the remainder of the episode, those 60-day episodes were simulated into one or two 30-day periods of care and are included in this year's proposed rule monitoring tables. Approximately, 6.1 percent of the 30-day periods of care in CY 2020 data were simulated because the original 60-day episode of care began in CY 2019 and ended in CY 2020. We remind readers, our preliminary analysis described in this section is not tied to any quality program.

(1) Utilization

We evaluate utilization by comparing our simulated 30-day periods in our analytical files, to actual CY 2020 PDGM claims, as described previously. The analytic files used for annual ratesetting do not include all 60-day episodes or 30-day periods of care because some of these episodes/periods are dropped for various reasons (for example, the claim could not be matched to an OASIS assessment). For all of the tables that follow, we examined utilization for CY 2018 simulated 30-day periods of care, CY 2019 simulated 30-day periods of care, and CY 2020 actual 30-day periods of care. Table 2 shows the overall utilization of home health over time. Table 3 shows utilization of visits per 30-day period of care by home health discipline over time. Preliminary data indicates while the number of 30-day periods of care decreased between CY 2018 and CY 2020, the average number of 30-day periods of care per unique HHA user is similar. Additionally, our preliminary data indicates, on average, the number of visits per 30-day period of care for all disciplines decreased between CY 2018 and CY 2020. On average, the total number of visits decreased by 1.27 visits per 30-day period of care between CY 2018 and CY 2020. Table 4 shows the proportion of 30-day periods of care that are LUPAs and the average number of visits per discipline of those LUPA 30-day periods of care over time.

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[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

TABLE 2: OVERALL UTILIZATION OF HOME HEALTH SERVICES, CYs 2018-2020

	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
30-Day Periods of Care	9,336,898	8,744,171	8,165,402
Unique HHA Users	2,980,385	2,802,560	2,786,662
Average Number of 30-Day Periods of care per Unique HHA User	3.13	3.12	2.93

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health Limited Data Set (LDS) file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the Chronic Conditions Data Warehouse (CCW) Virtual Research Data Center (VRDC) on March 30, 2021.

Notes: There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in this analysis. All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 3: UTILIZATION OF VISITS PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE, CYs 2018-2020

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Skilled Nursing	4.53	4.49	4.35
Physical Therapy	3.30	3.33	2.71
Occupational Therapy	1.02	1.07	0.78
Speech Therapy	0.21	0.21	0.16
Home Health Aide	0.72	0.67	0.54
Social Worker	0.08	0.08	0.06
Total (all disciplines)	9.86	9.85	8.59

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

Notes: There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in this analysis. All 30-day periods of care were included (for example LUPAs, PEPs, and outliers).

TABLE 4: THE PROPORTION OF 30-DAY PERIODS OF CARE THAT ARE LUPAs AND THE AVERAGE NUMBER OF VISITS BY HOME HEALTH DISCIPLINE FOR LUPA HOME HEALTH PERIODS, CYs 2018-2020

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Total percentage of overall 30-day periods of care that are LUPAs	6.7%	6.8%	8.6%
Discipline (Average # of visits for LUPA home health periods)			
Skilled Nursing	1.15	1.14	1.19
Physical Therapy	0.43	0.46	0.53
Occupational Therapy	0.07	0.07	0.08
Speech Therapy	0.02	0.02	0.02
Home Health Aide	0.01	0.01	0.01
Social Worker	0.01	0.01	0.01

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

Notes: The average (CY 2018 to CY 2020) number of visits per 30-day periods of care across all claims for skilled nursing is 4.46, for physical therapy is 3.13, for occupational therapy is 0.97, for speech therapy is 0.19, for home health aid is 0.65, and for social worker is 0.07. There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in this analysis.

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(2) Analysis of 2019 Cost Report Data for 30-Day Periods of Care

In the CY 2020 HH PPS final rule with comment period (84 FR 60483), we provided a summary of analysis on fiscal year (FY) 2017 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments; the CY 2020 30-day payment amount and estimated, average HHA costs for a 30-day period of care. In that rule, we utilized FY 2017 cost reports and CY 2017 home health claims to estimate both 60-day episode of care and 30-day period of care costs. We then updated the estimated CY 2017 60-day episode costs and 30-day period of care costs by the home health market basket update, reduced by the productivity adjustment for CYs 2018, 2019 and 2020 to calculate the 2020 estimated 60-day episode and 30-day period of care costs. As stated in the CY 2020 HH PPS final rule with comment period (84 FR 60485), we estimated that the CY 2020 30-day payment amount was approximately 16 percent higher than the average costs for a 30-day period of care. In MedPAC's March 2020 Report to Congress,[2] their review of home health payment adequacy found that ''access is more than adequate in most areas and that Medicare payments are substantially in excess of costs''.

In this proposed rule, we examined 2019 HHA Medicare cost reports, as this is the most recent and complete cost report data at the time of rulemaking, and CY 2020 30-day period of care home health claims, to estimate 30-day period of care costs. We excluded LUPAs and PEPs in the average number of visits. The 2019 average NRS costs per visit is $3.94. We updated the estimated 30-day period of care costs, 2019 average costs per visit with NRS by the CY 2020 home health market basket update, reduced by the productivity adjustment of 2.6 percent. Table 5 shows the estimated average costs for 30-day periods of care by discipline with NRS and the total 30-day period of care costs with NRS for CY 2020.

[2] *http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch9_sec.pdf?sfvrsn=0.*

TABLE 5: ESTIMATED COSTS FOR 30-DAY PERIODS OF CARE IN CY 2020

Discipline	2019 Average Costs per visit with NRS	2020 Average Number of Visits	2020 Market Basket Update	2020 Estimated 30-Day Period Costs
Skilled Nursing	$142.75	4.66	1.026	$682.51
Physical Therapy	$160.85	2.92	1.026	$481.89
Occupational Therapy	$160.14	0.85	1.026	$139.66
Speech Pathology	$181.27	0.17	1.026	$31.62
Medical Social Services	$238.66	0.06	1.026	$14.69
Home Health Aides	$73.20	0.59	1.026	$44.31
Total				$1,394.68

Source: 2019 Medicare cost report data obtained on January 26, 2021. Home health visit information came from episodes ending on or before December 31, 2019 (obtained from the CCW VRDC on July 13, 2020).
Note: The 2020 average number of visits excludes LUPAs and PEPs.

The CY 2020 national, standardized 30-day period payment rate was $1,864.03, which is approximately 34 percent more than the estimated CY 2020 30-day period cost of $1,394.68. Note that in the CY 2020 HH PPS final rule with comment period (84 FR 60484), the estimated average number of visits for a 30-day period of care in 2017 was estimated to be 10.5 visits. Using actual CY 2020 claims data, the average number of visits in a 30-day period was 9.25 visits—a decrease of approximately 12 percent. We recognize that with the COVID–19 PHE, the 2019 data on the Medicare cost reports may not reflect the most recent changes such as increased telecommunications technology costs, increased personal protective equipment (PPE) costs, and hazard pay. In its March 2021 Report to Congress, to estimate Medicare margins for 2021, MedPAC assumed a cost growth of 3 percent for CY 2020 (2 percentage points due to inflation and higher expenses for PPE and telehealth and 1 percentage point due to temporary surge pricing for PPE and other temporary costs of the PHE).[3] Furthermore, MedPAC noted that for more than a decade, payments under the HH PPS have significantly exceeded HHAs' costs primarily due to two factors—agencies reducing visits to reduce episode costs and cost growth in recent years has been lower than the annual payment updates.[4] As shown in Table 3 in this proposed rule, HHAs have reduced visits under the PDGM in CY 2020. When the 2020 cost reports become available, we will update the estimated 30-day period of care costs in CY 2020 in future rulemaking.

[3] *http://www.medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf?sfvrsn=0.*

[4] Ibid.

(3) Clinical Groupings and Comorbidities

Each 30-day period of care is grouped into one of 12 clinical groups, which describe the primary reason for which patients are receiving home health services under the Medicare home health benefit. The clinical grouping is based on the principal diagnosis reported on the home health claim. Table 6 shows the distribution of the 12 clinical groups over time. We also include the average case-mix weight for all 30-day periods in each of the clinical groups in CY 2020. In other words, the average case-mix weight for each clinical group includes all possible comorbidity adjustments, admission source and timing, and functional impairment levels. We refer readers to Table 16 in the CY 2020 HH PPS final rule with comment period (84 FR 60522 through 60533) for the CY 2020 PDGM LUPA threshold and case mix weight for each HHRG payment group.

TABLE 6: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY THE 12 PDGM CLINICAL GROUPS, CYs 2018-2020

Clinical Grouping	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	Average Case-mix Weight for Each Group
Behavioral Health	1.7%	1.5%	2.3%	0.8243
Complex	2.6%	2.5%	3.5%	0.8574
MMTA – Cardiac	16.5%	16.1%	19.0%	0.9202
MMTA – Endocrine	17.3%	17.4%	7.2%	1.0161
MMTA – GI/GU	2.2%	2.3%	4.7%	0.9793
MMTA – Infectious	2.9%	2.7%	4.8%	0.9805
MMTA – Other	4.7%	4.7%	3.1%	0.9711
MMTA – Respiratory	4.3%	4.1%	7.8%	0.9906
MMTA – Surgical Aftercare	1.8%	1.8%	3.5%	1.0701
MS Rehab	17.1%	17.3%	19.4%	1.1174
Neuro	14.4%	14.5%	10.5%	1.1603
Wound	14.5%	15.1%	14.2%	1.1923

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

Note: The average case mix weight for each clinical group includes all 30-day periods regardless of other adjustments (for example admission source, timing, comorbidities, etc.)

Thirty-day periods will receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use. We refer readers to section II. of this proposed rule and the CY 2020 final rule with comment period (84 FR 60493) for further information on the categories of the comorbidity adjustment. Home health 30-day periods of care can receive a low or a high comorbidity adjustment, or no comorbidity adjustment. Table 7 shows the distribution of 30-day periods of care by comorbidity adjustment category for all 30-day periods. We also include the average case-mix weight for each of the comorbidity adjustments in CY 2020. In other words, the average case-mix weight for each comorbidity adjustment includes all possible clinical groupings, admission source and timing, and functional impairment levels.

TABLE 7: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY COMORBIDITY ADJUSTMENT CATEGORY FOR 30-DAY PERIODS, CYs 2018-2020

Comorbidity Adjustment	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	Average Case-mix Weight for Each Group
None	55.6%	52.0%	49.2%	1.0058
Low	35.3%	38.0%	36.9%	1.0446
High	9.2%	10.0%	14.0%	1.1683

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

Note: The average case mix weight for each clinical group includes all 30-day periods regardless of other adjustments (for example admission source, timing, clinical group, etc.)

(4) Admission Source and Timing

Each 30-day period of care is classified into one of two admission source categories—community or institutional—depending on what healthcare setting was utilized in the 14 days prior to receiving home health care. Thirty-day periods of care for beneficiaries with any inpatient acute care hospitalizations, inpatient psychiatric facility (IPF) stays, skilled nursing facility (SNF) stays, inpatient rehabilitation facility (IRF) stays, or long-term care hospital (LTCH) stays within 14 days prior to a home health admission are designated as institutional admissions. Thirty-day periods of care are classified as ''early'' or ''late'' depending on when they occur within a sequence of 30-day periods of care. The first 30-day period of care is classified as early and all subsequent 30-day periods of care in the sequence (second or later) are classified as late. A subsequent 30-day period of care would not be considered early unless there is

a gap of more than 60 days between the end of one previous period of care and the start of another. Information regarding the timing of a 30-day period of care comes from Medicare home health claims data and not the OASIS assessment to determine if a 30-day period of care is ''early'' or ''late''. Table 8 shows the distribution of 30-day periods of care by admission source and timing over time. We also include the average case-mix weight for each of the admission source and period timing in CY 2020. In other words, the average case-mix weight for each admission source and period timing includes all possible clinical groupings, comorbidity adjustment, and functional impairment levels. We refer readers to Table 16 in the CY 2020 HH PPS Final Rule with comment period (84 FR 60522 through 60533) for the CY 2020 PDGM LUPA threshold and case mix weight for each HHRG payment group.

TABLE 8: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY ADMISSION SOURCE AND PERIOD TIMING, CYs 2018-2020

Admission Source	Period Timing	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	Average Case-mix Weight for Each Group
Community	Early	13.5%	13.8%	12.5%	1.2584
Community	Late	61.1%	60.9%	61.9%	0.8504
Institutional	Early	18.6%	18.4%	19.9%	1.4234
Institutional	Late	6.8%	6.9%	5.8%	1.3303

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

(5) Functional Impairment Level

Each 30-day period of care is placed into one of three functional impairment levels (low, medium, or high) based on responses to certain OASIS functional items associated with grooming, bathing, dressing, ambulating, transferring, and risk for hospitalization. The specific OASIS items that are used for the functional impairment level are found in Table 7 in the CY 2020 HH PPS final rule with comment period (84 FR, 60490). Responses to these OASIS items are grouped together into response categories with similar resource use and each response category has associated points. A more detailed description as to how these response categories were established can be found in the technical report, ''Overview of the Home Health Groupings Model'' posted on the HHA web page.[5] The sum of these points' results in a functional impairment level score used to group 30-day periods of care into a functional impairment level with similar resource use. The scores associated with the functional impairment levels vary by clinical group to account for differences in resource utilization. The functional impairment level will remain the same for the first and second 30-day periods of care unless there has been a significant change in condition which that warranted an ''other follow-up'' assessment prior to the second 30-day period of care. For each 30-day period of care, the Medicare claims processing system will look for the most recent OASIS assessment based on the claims ''from date.'' Table 9 shows the distribution of 30-day periods by functional status. We also include the average case-mix weight for each functional impairment level in CY 2020. In other words, the average case-mix weight for each functional impairment level includes all possible clinical groupings, comorbidity adjustment, and admission source and period timing. We refer readers to Table 16 in the CY 2020 HH PPS Final Rule with comment period (84 FR 60522 through 60533) for the CY 2020 PDGM LUPA threshold and case mix weight for each HHRG payment group.

TABLE 9: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY FUNCTIONAL IMPAIRMENT LEVEL, CYs 2018-2020

Functional Impairment Level	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	Average Case mix Weight for Each Group
Low	33.9%	31.9%	25.6%	0.8392
Medium	34.9%	35.5%	32.7%	1.0373
High	31.2%	32.6%	41.7%	1.1724

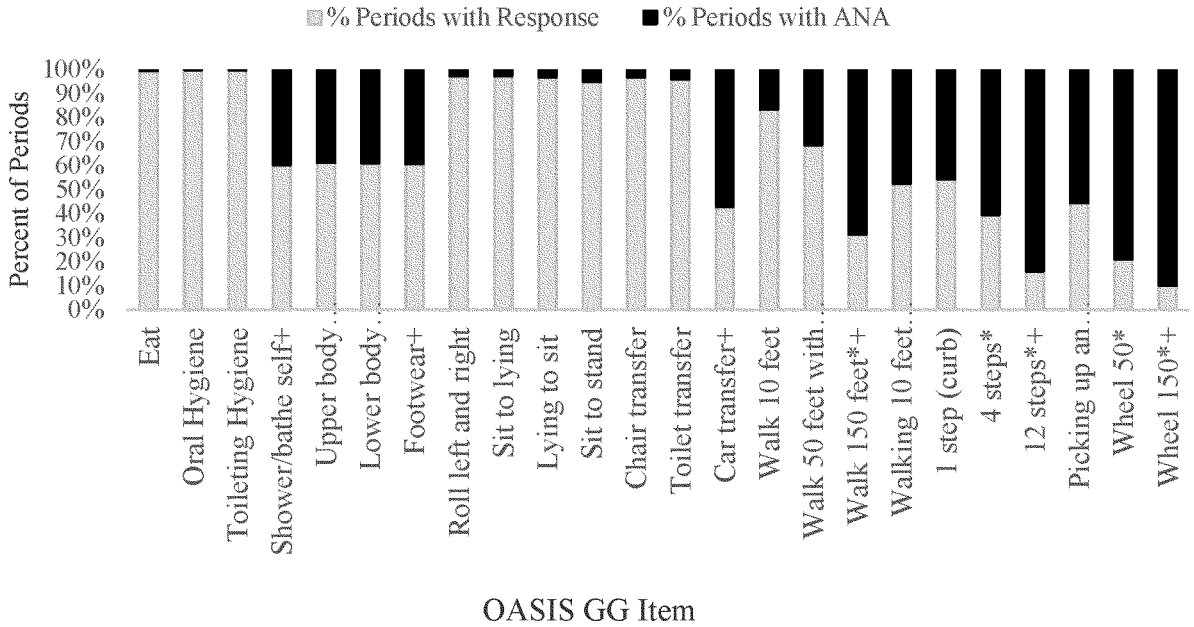
Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

[5] Overview of the Home Health Groupings Model. November 18, 2016. *https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf.*

Currently, the functional impairment level is determined by responses to certain OASIS items associated with functional activities of daily living and risk of hospitalization; that is, responses to OASIS items M1800–M1860 and M1032. However, the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, enacted on October 6, 2014) amended Title XVIII of the Act to include enacting new data reporting requirements for certain post-acute care (PAC) providers, including HHAs. Sections 1899B(b)(1)(A) of the Act requires the Secretary to require home health agencies to report standardized patient assessment data beginning no later than January 1, 2019. The standardized patient assessment data categories include functional status, such as mobility and self-care at admission and discharge, in accordance with 1899B(b)(1)(B)(i) of the Act. As such, CMS finalized adding the functional items, Section GG, ''Functional Abilities and Goals'', to the OASIS data set, effective January 1, 2019, in order to be able to measure functional status across PAC providers. At the time of CY 2020 rulemaking, we did not yet have the data to determine the effect, if any, of these newly added items on resource costs utilization during a home health period of care for use in the PDGM. Therefore, the GG functional items are not currently used to determine the functional impairment level under the PDGM.

We have examined the correlation between the current functional items used for payment (that is, M1800–1860) and the analogous GG items. We note that M1032, Risk for Hospitalization, does not have a corresponding GG item. Our preliminary analysis shows there is a correlation between the current responses to the M1800–1860 items and the GG items. However, there are certain information in M1800 items that are being collected at follow-up that are not collected with GG items (for example, the M1800 items associated with upper and lower body dressing are collected at follow up). Additionally, the GG items include an ''Activity Not Attempted'' (ANA) option, meaning the clinician did not put a response for the patient. Furthermore, there are a variety of ANA responses, including ''Not attempted due to medical or safety concerns'', and ''Not applicable''. Figure 2 shows the frequencies by response type in CY 2020 to the OASIS GG items.

FIGURE 2: OASIS GG ITEM FREQUENCIES BY RESPONSE TYPE IN CY 2020



Source: CY 2020 home health periods linked to OASIS data accessed from the CCW VRDC on March 30, 2021. Sample composed of 8,791,804 home health periods ending in 2020.
Notes: +Item is not collected on the follow-up assessment. *Item is skipped if a prior item has an ANA response. Wheel 50 and Wheel 150 are skipped if the patient is not indicated as using a wheelchair.

Our analysis of the GG items shows a significant amount of these ANA responses, making it difficult to map to the corresponding M1800–1860 item responses. Therefore, we will continue to monitor the GG items to determine the correlation between the current functional items used to case-mix adjust home health payments and the GG items, and we will provide additional analysis of the GG functional items in future rulemaking.

(6) Therapy Visits

Beginning in CY 2020, section 1895(b)(4)(B)(ii) of the Act eliminated the use of therapy thresholds in calculating payments for CY 2020 and subsequent years. Prior to implementation of the PDGM, HHAs could receive an adjustment to payment based on the number of therapy visits provided during a 60-day episode of care. As such, we examined the proportion of simulated 30-day periods with and without any therapy visits for CYs 2018 and 2019, prior to the removal of therapy thresholds. We also examined the proportion of actual 30-day periods of care with and without therapy visits for CY 2020, after the removal of therapy thresholds. To be

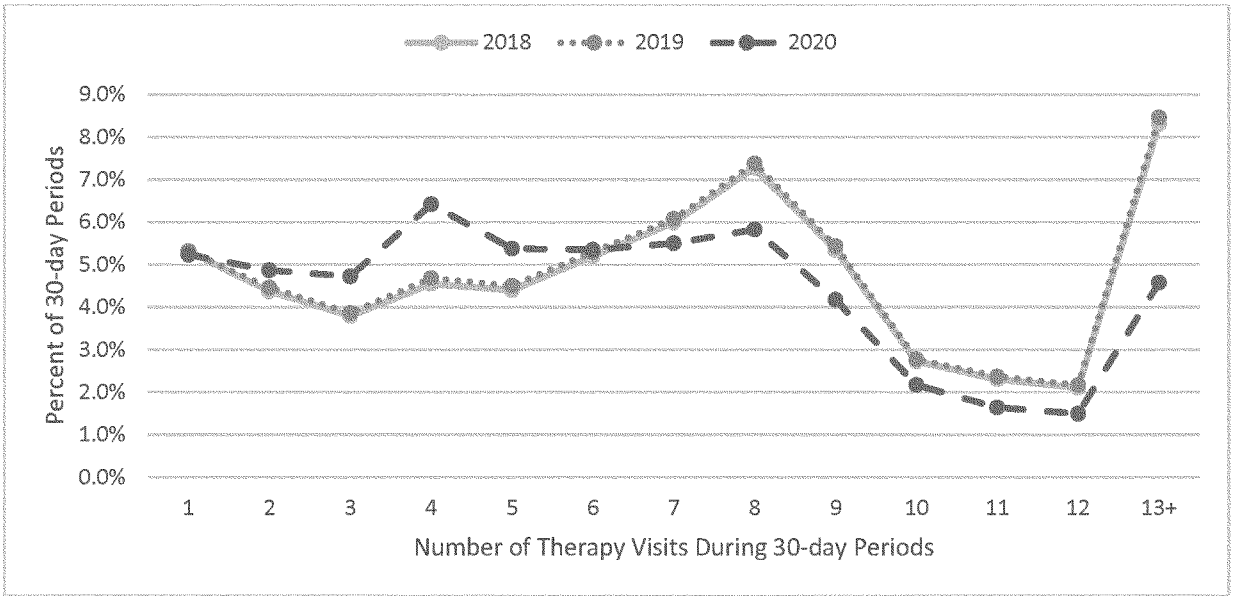
covered as skilled therapy, the services must require the skills of a qualified therapist (that is, PT, OT, or SLP) or qualified therapist assistant and must be reasonable and necessary for the treatment of the patient's illness or injury.[6] As shown in Table 3, we are monitoring the number of visits per 30-day periods of care by each home health discipline. Any 30-day period of care can include both therapy and non-therapy visits. If any 30-day period of care consisted of only visits for PT, OT, and/or SLP, then this 30-day period of care is considered ''therapy only''. If any 30-day period of care consisted of only visits for skilled nursing, home health aide, or social worker, then this 30-day period of care is considered ''no therapy''. If any 30-day period of care consisted of at least one therapy visit and one non-therapy, then this 30-day period of care is considered ''therapy + non-therapy''. Table 10 shows the proportion of 30-day periods of care with only therapy visits, at least one therapy visit and one non-therapy visits, and no therapy visits. Figure 3 shows the proportion of 30-day periods of care by the number of therapy visits (excluding zero) provided during 30-day periods of care.

TABLE 10: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY THERAPY, AT LEAST ONE THERAPY VISITS, AND NO THERAPY VISIT FOR CY 2018-2020

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Therapy Only	13.5%	14.4%	15.2%
Therapy + Non-therapy	48.2%	48.4%	42.2%
No Therapy	38.3%	37.2%	42.6%
Total 30-day periods	9,336,898	8,744,171	8,165,402

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

FIGURE 3: PROPORTION OF 30-DAY PERIODS OF CARE BY THE NUMBER OF THERAPY VISITS DURING 30-DAY PERIODS, CYs 2018-2020.



Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021 and includes all months of data.
Notes: Thirty-day periods of care with ≥13 therapy visits were combined into one category for illustrative purposes only

Both Table 10 and Figure 3, as previously discussed, indicate there have been changes in the distribution of both therapy and non-therapy visits in CY 2020. For example, the percent of 30-day periods with six or less therapy

[6] Medicare Benefit Policy Manual, Chapter 7 Home Health Services, Section 40.2 Skilled Therapy Services *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf.*

visits during a 30-day period increased in CY 2020. However, the percent of 30-day periods with seven or more therapy visits decreased in CY 2020.

In addition, we also examined the proportion of 30-day periods of care with and without skilled nursing, social work, or home health aide visits for CYs 2018, 2019 and 2020. Table 11 shows the number of 30-day periods of care with only skilled nursing visits, at least one skilled nursing visit and one other visit type (therapy or non-therapy), and no skilled nursing visits. Table 13 shows the number of 30-day periods of care with and without home health aide and/or social worker visits.

TABLE 11: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY SKILLED NURSING, SKILLED NURSING + OTHER VISIT TYPE, AND NO SKILLED NURSING VISITS FOR CYs 2018-2020

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Skilled Nursing Only	33.8%	33.1%	38.6%
Skilled Nursing + Other	51.6%	51.5%	45.2%
No Skilled Nursing	14.7%	15.5%	16.2%
Total 30-day periods	9,336,898	8,744,171	8,165,402

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

TABLE 12: PROPORTION OF 30-DAY PERIODS OF CARE WITH AND WITHOUT HOME HEALTH AIDE AND/OR SOCIAL WORKER VISITS FOR CYs 2018-2020

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020
Any HH aide and/or social worker	16.6%	15.9%	13.1%
No HH aide and/or social worker	83.4%	84.1%	86.9%
Total 30-day periods	9,336,898	8,744,171	8,165,402

Source: Analysis of data for CY 2018 through CY 2020. CY 2018 and CY 2019 data came from the Home Health LDS file and we applied the three behavioral assumptions to half the claims (randomly selected). CY 2020 was accessed from the CCW VRDC on March 30, 2021.

We will continue to monitor the provision of home health services, including any changes in the number and duration of home health visits, composition of the disciplines providing such services, and overall home health payments to determine if refinements to the case-mix adjustment methodology may be needed in the future.

We solicit public comments on the preliminary data analysis presented in this rule and we solicit comments on whether there are other analyses that should be conducted to examine the effects of the PDGM on home health expenditures and utilization.

2. Comment Solicitation on the Annual Determination of the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Payment Expenditures Under the HH PPS

a. Background

Section 1895(b)(3)(A)(iv) of the Act, required CMS, with respect to payments for home health units of service furnished that end during the 12-month period beginning January 1, 2020, to calculate a standard prospective payment amount (or amounts) for 30-day units of service in a manner such that the estimated aggregate amount of expenditures would be equal to the estimated aggregate amount of expenditures that otherwise would have been made had the 30-day unit of payment not been enacted. In calculating such amount (or amounts), CMS was required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors that eliminated the use of therapy thresholds. CMS was to provide a description of such assumptions through notice and comment rulemaking.

In the CY 2019 HH PPS final rule with comment period (83 FR 56454), as required by law, we stated that this means we were required to calculate a 30-day period payment amount for CY 2020 in a budget neutral manner such that estimated aggregate expenditures under the HH PPS during CY 2020 were equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of payment and the implementation of the PDGM case-mix adjustment methodology. This means

that aggregate Medicare payments under the new 432-group payment system and 30-day unit of payment would be the same as they would have been under the 153-group payment system and 60-day unit of payment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior assumptions in order to calculate a 30-day budget-neutral payment amount for CY 2020:

- *Clinical Group Coding:* The clinical group is determined by the principal diagnosis code for the patient as reported by the HHA on the home health claim. This behavior assumption assumes that HHAs will change their documentation and coding practices and put the highest paying diagnosis code as the principal diagnosis code in order to have a 30-day period be placed into a higher-paying clinical group.
- *Comorbidity Coding:* The PDGM further adjusts payments based on patients' secondary diagnoses as reported by the HHA on the home health claim. The OASIS only allows HHAs to designate 1 principal diagnosis and 5 secondary diagnoses while the home health claim allows HHAs to designate 1 principal diagnosis and up to 24 secondary diagnoses. This behavior assumption assumes that by taking into account additional ICD–10–CM diagnosis codes listed on the home health claim (beyond the 6 allowed on the OASIS), more 30-day periods of care will receive a comorbidity adjustment.
- *LUPA Threshold:* This behavior assumption assumes that for one-third of LUPAs that are 1 to 2 visits away from the LUPA threshold HHAs will provide 1 to 2 extra visits to receive a full 30-day payment.

There are overlaps and interactions between these behavior assumptions, and when combined, the budget-neutral payment amount for CY 2020 resulted in a proposed −8.389 percent adjustment to the 30-day period payment amount compared to the payment amount calculated in a budget neutral manner without these assumptions applied. In response to the proposed rule, commenters stated that CMS overestimated the magnitude of the assumed behavior changes. We reconsidered the frequency of the assumed behaviors during the first year of the transition to the new unit of payment and case-mix adjustment methodology in response to these comments, and in the CY 2020 HH PPS final rule with comment period (84 FR 60519), we finalized a −4.36 percent behavior assumption adjustment in order to calculate a national, standardized 30-day base payment rate. After applying the wage index budget neutrality factor and the home health payment update, the CY 2020 30-day payment rate was set at $1,864.03, and for determining outlier payments the fixed-dollar loss (FDL) ratio was set at 0.56.

Section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures beginning with 2020 and ending with 2026. In the CY 2020 final rule (84 FR 60513), we stated that we interpret actual behavior changes to encompass both behavior changes that were previously outlined, as assumed by CMS, and other behavior changes not identified at the time that the budget neutral 30-day payment for CY 2020 was determined. As required by 1895(b)(3)(D)(ii) of the Act, the Secretary shall, at a time and in a manner determined appropriate, through notice and comment rulemaking, provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures.

As required by section 1895(b)(3)(D)(iii) of the Act, the Secretary shall, at a time and in a manner determined appropriate, through notice and comment rulemaking, provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing such amount for a subsequent year. That is, we are required to retrospectively determine if the 30-day payment amount in CY 2020 resulted in the same level of estimated aggregate expenditures that would have been made if the change in the unit of payment and the PDGM case-mix adjustment methodology had not been implemented, and make adjustments to the 30-day payment amount prospectively, if needed.

b. Methodology To Determine the Difference Between Assumed Versus Actual Behavior Changes on Estimated Aggregate Expenditures

Using CY 2020 data (as of March 30, 2021), the most recent, complete data available at the time of this proposed rule, we analyzed the impact of the differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures to determine whether a temporary and/or a permanent increase or decrease is needed to the national, standardized 30-day period payment in CY 2022. We analyzed data to determine if the CY 2020 30-day payment amount resulted in the same estimated aggregate expenditures that would have been paid if the PDGM and change in the unit of payment had not been implemented.

To evaluate if whether the 30-day budget neutral payment amount for CY 2020 maintained budget neutrality given the change to a 30-day unit of payment and the implementation of a new case-mix adjustment methodology without therapy thresholds was accurate, we used actual CY 2020 30-day period claims data to simulate 60-day episodes and we determined what CY 2020 payments would have been under the 153-group case-mix system and 60-day unit of payment. To do this, we used the steps outlined as follows as detailed in this section of this rule.

The first step in repricing CY 2020 PDGM claims was to determine which 30-day periods of care could be grouped together to form 60-day episodes of care. To facilitate grouping, we made some exclusions and assumptions.

(1) Exclusions

We limited the sample to 30-day periods where the claim occurrence code 50 date (representing the OASIS assessment date) occurred on or before October 31, 2020. This was done to ensure the simulated 60-day episodes we constructed contained both 30-day periods and would not be simulated 60-day episodes that would have overlapped into 2021.

We excluded the following:

- Beneficiaries and all of their claims if they had overlapping claims from the same provider (as identified by CCN).[7]
- Beneficiaries and all of their claims if three or more claims from the same provider are linked to the same occurrence code 50 date.[8]

(2) Assumptions

We assumed the following:

- If two 30-day periods of care from the same provider reference the same

[7] All of a beneficiary's claims were dropped so as not to create problems with assigning episode timing if only a subset of claims were dropped. 1,320 claims from 224 beneficiaries are excluded.

[8] This was done because if three or more claims linked to the same OASIS it would not be clear which claims should be joined to simulate a 60-day episode. 11,794 claims from 351 beneficiaries are excluded.

OASIS assessment date (using occurrence code 50), and then we assume those two 30-day periods of care would have been billed as a 60-day episode of care under the 153-group system.

- If there are two 30 day-periods of care that reference different OASIS assessment dates and each of those assessment dates is referenced by a single 30-day period of care and those two 30-day periods of care occur together close in time (that is, the from date of the later 30-day period of care is between 0 to 14 days after the through date of the earlier 30-day period of care), then we assume those two 30-day periods of care also would have been billed as a 60-day episode of care under the 153-group system.
- For all other 30-day periods of care, we assumed that they would not be combined with another 30-day period of care and would have been billed alone. We excluded such periods that occurred at the start of the year (January 1, 2020–January 14, 2020) or end of the year (December 1–31, 2020) so as not to count a single 30-day period of care that may have had a counterpart that could not be observed.

Once we applied our exclusions and assumptions, we assigned each 60-day episode of care as a normal episode, PEP, LUPA, or outlier based on the payment parameters established in the CY 2020 final rule with comment period (84 FR 60478) for 60-day episodes of care. Next, using the 3M Home Health Grouper (v8219) we assigned a Health Insurance Prospective Payment System (HIPPS) code to each simulated 60-day episode of care using the 153-group methodology. Finally, we priced out the simulated 60-day episodes of care using the payment parameters described in the CY 2020 final rule with comment period (84 FR 60537) for 60-day episodes of care. Before comparing payments for the 30-day periods of care using the 432-group PDGM methodology, we first removed any claim that was excluded in the simulated 60-day episode dataset. Therefore, our comparison between payments had the same utilization between the CY 2020 simulated 60-day episodes of care and the CY 2020 actual 30-day periods of care.

We began with 8,165,808 30-day periods of care and dropped 524,163 30-day periods of care that had a claim occurrence code 50 date after October 31, 2020. We also eliminated 81,641 30-day periods of care that appeared to not group with another 30-day period of care to form a 60-day episode of care if the 30-day period of care had a ''from date'' before January 15, 2020 or a ''through date after'' November 30, 2020. This was done to ensure the 30-day period of care would not have been part of a 60-day episode of care that would have spanned into a prior or subsequent year. As described previously, we excluded claims and made assumptions when combining two 30-day periods of care. Additionally, any simulated 60-day episode of care where no OASIS information was available or could not be grouped to a HIPPS due to a missing primary diagnosis or other reason was excluded from analysis. Our simulated 60-day episodes of care produced a distribution between two 30-day periods of care (69.8 percent) and single 30-day periods of care (30.2 percent) that was similar to what we found when we simulated two 30-day periods of care for implementation of the PDGM. After all exclusions and assumptions were applied, the final dataset included 7,441,602 actual 30-day periods of care and 4,378,823 simulated 60-day episodes of care for CY 2020.

For the simulated 60-day episodes of care and before any adjustment for PEP, LUPA, or outliers were applied, payments were calculated using the CY 2020 153-group 60-day base payment rate of $3,220.79, the 153-group case-mix adjustment methodology, and FDL of 0.51, as described in the CY 2020 HH PPS final rule with comment period (84 FR 60537). For the actual 30-day periods of care that constructed the simulated 60-day episodes of care and before any adjustment for PEP, LUPA, or outliers were applied, payments were calculated using the CY 2020 30-day base payment rate of $1,864.03, the 432-group PDGM case-mix adjustment methodology, and FDL of 0.56 as described in the CY 2020 final rule with comment period (84 FR 60539). After the claims in the simulated 60-day episodes of care and 30-day periods of care were priced using the payment rates described previously, we calculated the total payments for all periods, normal periods, PEPs, LUPAs, and outliers (excluding the base payment to ensure outlier payments were no more than 2.5 percent of total estimated HH PPS payments). Our preliminary results indicated that aggregate payments to HHAs were higher in CY 2020 under the PDGM case-mix adjustment methodology and the 30-day unit of payment compared to what HHAs would have been paid had the PDGM and 30-day unit of payment not been implemented.

Next, we calculated what the CY 2020 30-day periods of care base payment rate and FDL should have been, to achieve the estimated aggregate payments for the simulated 60-day episodes in CY 2020. We then calculated a percent change between the payment rates. In other words, we divided the CY 2020 repriced 30-day base payment rate by the actual CY 2020 base-payment rate minus one. We determined the CY 2020 30-day base payment rate was approximately 6 percent higher than it should have been, and would require temporary retrospective adjustments for CY 2020 and subsequent years until a permanent prospective adjustment could be implemented in future rulemaking.

One of the driving factors between what we paid HHAs under the current 432-group PDGM methodology with a 30-day unit of payment and what we would have paid HHAs under the previous 153-group case-mix adjustment methodology with a 60-day unit of payment is related to the average case-mix weights. The average case-mix weight for the 30-day periods of care used to construct the simulated 60-day of care episodes was 1.0310; compared to the average case-mix weight for the simulated 60-day of care episodes was 0.9657, a difference of 0.0653. As the difference between the two average case-mix weights increases (that is, farther from zero) the higher the difference in payments; conversely as the difference between the two average case-mix weights decreases (that is, closer to zero) the smaller the difference in payments. HHAs should be providing visits in accordance with patient care needs.

The law provides flexibility for the Secretary to make an increase or decrease adjustment to the 30-day payment amount to offset any difference between assumed versus actual behavior of estimated aggregate expenditures, at a time and manner determined appropriate and allows for prospective adjustments based on retrospective behavior. As stated previously, currently our preliminary analysis shows an additional payment decrease would more appropriately account for behaviors reflected in CY 2020, after the implementation of the PDGM and 30-day unit of payment. However, we anticipate potentially seeing further variability in this percentage as we continue to analyze full claims data from CY 2020 and subsequent years, and considering that the COVID–19 PHE is still ongoing. We intend to propose a methodology and, if appropriate, a temporary and permanent payment adjustment based on our analysis in future rulemaking. However, we note that by not proposing any adjustment for CY 2022, this could potentially result in larger, compounding payment adjustments in future years to fully

account for the difference between assumed versus actual behavior change on estimated aggregate expenditures beginning in CY 2020.

We recognize that stakeholders may have other ways to analyze the data to determine the difference between assumed versus actual behavior change on estimated aggregate expenditures, such as analysis of nominal case-mix growth or calculating the percent difference and percent change of payments between simulated 30-day periods of care and actual 30-day periods of care. We solicit comments on the described repricing method for evaluating budget neutrality for CY 2020 and any alternate approaches to annually determine the difference between assumed and actual behavioral changes on estimated aggregate expenditures under the HH PPS.

3. CY 2022 PDGM LUPA Thresholds and PDGM Case-Mix Weights

a. Proposed CY 2022 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. In the CY 2019 HH PPS final rule (83 FR 56492),) we finalized that the LUPA thresholds would be set at the 10th percentile of visits or 2 visits, whichever is higher, for each payment group. This means that the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care will be paid the full 30-day period case-mix adjusted payment amount (subject to any PEP or outlier adjustments). If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the CY 2022 per-visit payment amounts as described in Section III of this proposed rule. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or less visits, payment is made using the per-visit payment amounts.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group would be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, CY 2020 was the first year of the new case-mix adjustment methodology and we stated in the CY 2021 final rule (85 FR 70305, 70306) we would maintain the LUPA thresholds that were finalized and shown in Table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. At that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

We have received anecdotal feedback from stakeholders that in CY 2020, HHAs billed more LUPAs because patients requested fewer in-person visits due the COVID–19 PHE. As discussed further in this section of this rule, while we are proposing to update the case-mix weights for CY 2022 using CY 2020 data, there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups. CMS believes that the PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the PHE on the calculation of the case-mix weight would be minimized since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that would control for the impacts of the PHE. We note that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. If we were to set the LUPA thresholds in this proposed rule using CY 2020 data and then set the LUPA thresholds again for CY 2023 using data from CY 2021, it is likely that there would be an increase in these thresholds due to the lower number of visits that occurred in CY 2020. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID–19 PHE, we are proposing to maintain the LUPA thresholds finalized and displayed in Table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes. We believe that maintaining the LUPA thresholds for CY 2022 is the best approach because it mitigates potential fluctuations in the thresholds caused by visit patterns changing from what we observed in CY 2020 potentially due to the PHE. We will repost these LUPA thresholds (along with the case-mix weights) that will be used for CY 2022 on the HHA Center web page.[9] We solicit public comments on maintaining the LUPA thresholds for CY 2022 payment purposes.

b. CY 2022 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization; that is, responses to OASIS items M1800–M1860 and M1032. A home health period of care receives points based on each of the responses associated with these functional OASIS items, which are then converted into a table of points corresponding to increased resource use. The sum of all of these points results in a functional score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the higher the response is associated with increased resource use. The sum of all of these points results in a functional impairment score which is used to group home health periods into one of three functional impairment levels with similar resource use. The three functional impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each of the clinical groups fall within each level. This means home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2022, we propose to use CY 2020 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS Proposed rule (82 FR 35320) and the HHGM technical report from December 2016 posted on the HHA Center web page provide a more detailed explanation as to the construction of these functional impairment levels using the OASIS items. We are proposing to use this same methodology previously finalized to update the functional impairment levels for CY 2022. The updated OASIS functional points table and the table of

[9] *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

functional impairment levels by clinical group for CY 2022 are listed in Tables 13 and 14, respectively. We solicit public comments on the updates to functional points and the functional impairment levels by clinical group.

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TABLE 13: OASIS POINTS TABLE FOR THOSE ITEMS ASSOCIATED WITH INCREASED RESOURCE USE USING A REDUCED SET OF OASIS ITEMS, CY 2020

	Responses	Points (2020)	Percent of Periods in 2020 with this Response Category
M1800: Grooming	0 or 1	0	33.8%
	2 or 3	3	66.2%
M1810: Current Ability to Dress Upper Body	0 or 1	0	28.8%
	2 or 3	6	71.2%
M1820: Current Ability to Dress Lower Body	0 or 1	0	13.6%
	2	5	63.3%
	3	12	23.0%
M1830: Bathing	0 or 1	0	3.4%
	2	1	13.4%
	3 or 4	9	51.4%
	5 or 6	17	31.7%
M1840: Toilet Transferring	0 or 1	0	63.7%
	2, 3 or 4	5	36.3%
M1850: Transferring	0	0	2.0%
	1	3	24.3%
	2, 3, 4 or 5	7	73.7%
M1860: Ambulation/Locomotion	0 or 1	0	4.5%
	2	6	16.8%
	3	6	61.2%
	4, 5 or 6	19	17.5%
M1032: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	0	70.1%
	Four or more items marked (Excluding responses 8, 9 or 10)	12	29.9%

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW on March 30, 2021.

TABLE 14: THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, CY 2020

Clinical Group	Level of Impairment	Points (2020)
MMTA – Other	Low	0-32
	Medium	33-48
	High	49+
Behavioral Health	Low	0-32
	Medium	33-48
	High	49+
Complex Nursing Interventions	Low	0-35
	Medium	36-56
	High	57+
Musculoskeletal Rehabilitation	Low	0-35
	Medium	36-48
	High	49+
Neuro Rehabilitation	Low	0-36
	Medium	37-55
	High	56+
Wound	Low	0-36
	Medium	37-53
	High	54+
MMTA - Surgical Aftercare	Low	0-33
	Medium	34-45
	High	46+
MMTA - Cardiac and Circulatory	Low	0-32
	Medium	33-47
	High	48+
MMTA - Endocrine	Low	0-30
	Medium	31-44
	High	45+
MMTA - Gastrointestinal tract and Genitourinary system	Low	0-36
	Medium	37-51
	High	52+
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	0-33
	Medium	34-48
	High	49+
MMTA - Respiratory	Low	0-36
	Medium	37-48
	High	49+

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW March 30, 2021.

c. CY 2022 Comorbidity Subgroups

Thirty-day periods of care receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the diagnoses have at least as high as the median resource use and are reported in more than 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to if they were reported separately. That is, the two diagnoses

may interact with one another, resulting in higher resource use.

- *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or none meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406) we stated that we would continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with the actual costs of providing care. For CY 2022, we propose to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2020 home health data.

For CY 2022, we propose to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups as identified in Table 15 and 85 high comorbidity adjustment interaction subgroups as identified in Table 16. The proposed CY 2022 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will also be posted on the HHA Center web page at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

We invite comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2022.

TABLE 15: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2022

Low Comorbidity Subgroup	Subgroup Description
Neoplasms 22	Includes lymphoma and leukemia
Musculoskeletal 2	Includes rheumatoid arthritis
Circulatory 7	Includes atherosclerosis and peripheral vascular disease
Neoplasms 2	Includes gastrointestinal cancers
Musculoskeletal 1	Includes lupus
Endocrine 4	Includes malnutrition and graft-versus-host-disease
Heart 10	Includes atrial fibrillation and atrial flutter.
Heart 11	Includes heart failure
Neurological 10	Includes diabetes with neuropathy
Neurological 11	Includes macular degeneration
Neoplasms 18	Includes secondary cancers
Neoplasms 1	Includes head and neck cancers
Circulatory 9	Includes embolisms and thromboses
Cerebral 4	Includes cerebral atherosclerosis and stroke sequelae
Skin 1	Includes cellulitis and abscesses
Neurological 5	Includes Parkinson's Disease
Circulatory 10	Includes varicose veins with ulceration
Neurological 7	Includes paraplegia, hemiplegia and quadriplegia
Skin 3	Includes chronic ulcers
Skin 4	Includes pressure ulcers

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW March 30, 2021.

TABLE 16: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2022

Comorbidity Subgroup Interaction	Comorbidity Group	Comorbidity Group
1	Neurological 4	Respiratory 9
2	Neurological 4	Neurological 5
3	Renal 1	Skin 3
4	Behavioral 2	Neurological 5
5	Cerebral 4	Neurological 10
6	Endocrine 3	Neurological 5
7	Neurological 3	Skin 3
8	Endocrine 5	neurological_7

Comorbidity Subgroup Interaction	Comorbidity Group	Comorbidity Group
9	Neurological 10	Neurological 5
10	Musculoskeletal 3	Neurological 7
11	Heart 12	Skin 3
12	Circulatory 9	Endocrine 4
13	Circulatory 4	Neurological 7
14	Circulatory 2	Neurological 5
15	Neurological 4	Skin 3
16	Cerebral 4	Neurological 5
17	Heart 11	Neurological 7
18	Neurological 5	Neurological 7
19	Circulatory 10	Heart 11
20	Circulatory 10	Endocrine 5
21	Circulatory 4	Skin 3
22	Neurological 10	Skin 3
23	Skin 1	Skin 3
24	Endocrine 1	Skin 3
25	Cerebral 4	Skin 3
26	Neurological 7	Renal 3
27	Musculoskeletal 4	Skin 3
28	Musculoskeletal 3	Skin 3
29	Heart 8	Skin 3
30	Circulatory 1	Neurological 7
31	Circulatory 7	Skin 3
32	Endocrine 3	Skin 3
33	Endocrine 5	Skin 3
34	Neurological 3	Skin 4
35	Circulatory 2	Neurological 7
36	Endocrine 4	Neurological 7
37	Renal 1	Skin 4
38	Cerebral 4	Skin 4
39	Circulatory 10	Skin 3
40	Infectious 1	Skin 4
41	Renal 3	Skin 4
42	Heart 10	Skin 4
43	Endocrine 4	Skin 4
44	Neurological 7	Skin 4
45	Skin 3	Skin 4
46	Cerebral 4	Circulatory 7
47	Circulatory 9	Renal 3
48	Circulatory 10	Endocrine 3
49	Circulatory 10	Heart 12
50	Behavioral 2	Neurological 7
51	Neurological 5	Skin 3
52	Neurological 4	Skin 4
53	Endocrine 5	Skin 1

Comorbidity Subgroup Interaction	Comorbidity Group	Comorbidity Group
54	Neurological 5	Renal 3
55	Cerebral 4	Heart 11
56	Infectious 1	Skin 3
57	Respiratory 5	Skin 4
58	Endocrine 1	Skin 4
59	Circulatory 10	Neurological 10
60	Circulatory 1	Skin 3
61	Musculoskeletal 2	Skin 3
62	Respiratory 4	Skin 3
63	Neurological 11	Skin 4
64	Behavioral 2	Skin 4
65	Circulatory 1	Neurological 5
66	Neurological 10	Skin 4
67	Heart 11	Skin 3
68	Respiratory 9	Skin 3
69	Circulatory 2	Skin 4
70	Cerebral 4	Circulatory 2
71	Circulatory 10	Endocrine 1
72	Heart 11	Skin 1
73	Circulatory 10	Neurological 11
74	Endocrine 5	Neurological 5
75	Musculoskeletal 3	Neurological 5
76	Heart 10	Skin 3
77	Behavioral 5	Skin 4
78	Circulatory 7	Neurological 5
79	Heart 10	Skin 1
80	Circulatory 10	Respiratory 5
81	Behavioral 5	Neurological 7
82	Musculoskeletal 4	Neurological 5
83	Neurological 11	Skin 1
84	Circulatory 9	Neurological 10
85	Circulatory 4	Skin 4

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW March 30, 2021.

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d. CY 2022 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called home health resource groups (HHRGs). We also finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56515) to annually recalibrate the PDGM case-mix weights using a fixed effects model with the most recent and complete utilization data available at the time of annual rulemaking. Annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. To generate the proposed recalibrated CY 2022 case-mix weights, we used CY 2020 home health claims data with linked OASIS data (as of March 30, 2021). These data are the most current and complete data available at this time. We believe that recalibrating the case-mix weights using data from CY 2020 would be more reflective of PDGM utilization and patient resource use than case-mix weights that were set using simulated claims data of 60-day

episodes grouped under the old system. Using data from CY 2020 would begin to shift case-mix weights derived from data with 60-day episodes grouped under the old system to data from actual 30-day periods under the PDGM.

The claims data provide visit-level data and data on whether NRS was provided during the period and the total charges of NRS. We determine the case-mix weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model as described in the following steps:

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM, which are obtained from certain OASIS items. We refer readers to Table 11 for further information on the OASIS items used for the functional impairment level under the PDGM. We measure resource use with the cost-per-minute + NRS approach that uses information from 2019 home health cost reports. We use 2019 home health cost report data because it is the most complete data available at the time of rulemaking. Other variables in the regression model include the 30-day period's admission source, clinical group, and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium or high functional impairment level. We set those thresholds so that we assign roughly a third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

Step 2: A second regression model estimates the relationship between a 30-day period's resource use and indicator variables for the presence of any of the comorbidities and comorbidity interactions that were originally examined for inclusion in the PDGM. Like the first regression model, this model also includes home health agency level fixed effects and includes control variables for each 30-day period's admission source, clinical group, timing, and functional impairment level. After we estimate the model, we assign comorbidities to the low comorbidity adjustment if any comorbidities have a coefficient that is statistically significant (p-value of 0.05 or less) and which have a coefficient that is larger than the 50th percentile of positive and statistically significant comorbidity coefficients. If two comorbidities in the model and their interaction term have coefficients that sum together to exceed $150 and the interaction term is statistically significant (p-value of 0.05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: Hold the LUPA thresholds at their current thresholds as described previously in this proposed rule.

Step 4: Take all non-LUPA 30-day periods and regress resource use on the 30-day period's clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. The regression includes fixed effects at the level of the home health agency. After we estimate the model, the model coefficients are used to predict each 30-day period's resource use. To create the case-mix weight for each 30-day period, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression.

The case-mix weight is then used to adjust the base payment rate to determine each 30-day period's payment. Table 17 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

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TABLE 17: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE (LUPA THRESHOLDS HELD)

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
MMTA - Other - Medium Functional	$168.75	1.2%	0.1173
MMTA - Other - High Functional	$328.92	0.9%	0.2286
MMTA - Surgical Aftercare - Low Functional	-$84.68	1.2%	-0.0589
MMTA - Surgical Aftercare - Medium Functional	$136.53	1.2%	0.0949
MMTA - Surgical Aftercare - High Functional	$373.88	1.1%	0.2598
MMTA - Cardiac and Circulatory - Low Functional	-$46.28	6.8%	-0.0322
MMTA - Cardiac and Circulatory - Medium Functional	$133.00	6.0%	0.0924
MMTA - Cardiac and Circulatory - High Functional	$287.68	6.5%	0.1999
MMTA - Endocrine - Low Functional	$283.93	2.5%	0.1973
MMTA - Endocrine - Medium Functional	$453.61	2.5%	0.3153
MMTA - Endocrine - High Functional	$560.18	2.4%	0.3893
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$71.18	1.8%	-0.0495
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$129.27	1.3%	0.0898
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$259.89	1.5%	0.1806
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$44.92	1.6%	-0.0312
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$130.02	1.7%	0.0904
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$319.67	1.5%	0.2222
MMTA - Respiratory - Low Functional	-$33.98	3.3%	-0.0236
MMTA - Respiratory - Medium Functional	$132.20	1.9%	0.0919
MMTA - Respiratory - High Functional	$283.71	2.5%	0.1972
Behavioral Health - Low Functional	-$117.70	0.8%	-0.0818
Behavioral Health - Medium Functional	$109.77	0.8%	0.0763
Behavioral Health - High Functional	$235.73	0.7%	0.1638
Complex - Low Functional	-$125.82	1.0%	-0.0874
Complex - Medium Functional	$76.72	1.1%	0.0533
Complex - High Functional	$49.15	1.0%	0.0342
MS Rehab - Low Functional	$103.23	6.6%	0.0717
MS Rehab - Medium Functional	$253.23	6.9%	0.1760
MS Rehab - High Functional	$485.44	6.0%	0.3374
Neuro - Low Functional	$260.97	3.6%	0.1814
Neuro - Medium Functional	$452.77	3.4%	0.3147
Neuro - High Functional	$628.16	3.5%	0.4366
Wound - Low Functional	$426.01	5.7%	0.2961
Wound - Medium Functional	$597.58	3.8%	0.4153
Wound - High Functional	$770.94	4.8%	0.5358
Admission Source with Timing (Community Early is excluded)			
Community – Late	-$568.10	62.9%	-0.3948
Institutional – Early	$308.04	19.4%	0.2141
Institutional – Late	$173.03	6.1%	0.1203
Comorbidity Adjustment (No Comorbidity Adjustment is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$92.90	48.1%	0.0646
Comorbidity Adjustment - Has at least one interaction from interaction list	$318.97	14.6%	0.2217
Constant	$1,365.18		
Average Resource Use	$1,438.86		
Number of 30-day Periods	7,365,743		
Adjusted R-Squared	0.3311		

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW March 30, 2021.

The case-mix weights proposed for CY 2022 are listed in Table 19 and will also be posted on the HHA Center web page [10] upon display of this proposed rule.

TABLE 18—CASE MIX WEIGHTS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
1AA11	MMTA - Other - Low	Early – Community	0	0.9488
1AA21	MMTA - Other - Low	Early – Community	1	1.0134
1AA31	MMTA - Other - Low	Early – Community	2	1.1705
1AB11	MMTA - Other - Medium	Early – Community	0	1.0661
1AB21	MMTA - Other - Medium	Early – Community	1	1.1306
1AB31	MMTA - Other - Medium	Early – Community	2	1.2877
1AC11	MMTA - Other - High	Early – Community	0	1.1774
1AC21	MMTA - Other - High	Early – Community	1	1.2420
1AC31	MMTA - Other - High	Early – Community	2	1.3991
1BA11	Neuro - Low	Early – Community	0	1.1302
1BA21	Neuro - Low	Early – Community	1	1.1947
1BA31	Neuro - Low	Early – Community	2	1.3518
1BB11	Neuro - Medium	Early – Community	0	1.2635
1BB21	Neuro - Medium	Early – Community	1	1.3280
1BB31	Neuro - Medium	Early – Community	2	1.4851
1BC11	Neuro - High	Early – Community	0	1.3854
1BC21	Neuro - High	Early – Community	1	1.4499
1BC31	Neuro - High	Early – Community	2	1.6070
1CA11	Wound - Low	Early – Community	0	1.2449
1CA21	Wound - Low	Early – Community	1	1.3094
1CA31	Wound - Low	Early – Community	2	1.4665

[10] HHA Center web page: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center*

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
1CB11	Wound - Medium	Early – Community	0	1.3641
1CB21	Wound - Medium	Early – Community	1	1.4287
1CB31	Wound - Medium	Early - Community	2	1.5858
1CC11	Wound - High	Early - Community	0	1.4846
1CC21	Wound - High	Early - Community	1	1.5492
1CC31	Wound - High	Early - Community	2	1.7063
1DA11	Complex - Low	Early - Community	0	0.8613
1DA21	Complex - Low	Early - Community	1	0.9259
1DA31	Complex - Low	Early - Community	2	1.0830
1DB11	Complex - Medium	Early - Community	0	1.0021
1DB21	Complex - Medium	Early - Community	1	1.0667
1DB31	Complex - Medium	Early - Community	2	1.2238
1DC11	Complex - High	Early - Community	0	0.9829
1DC21	Complex - High	Early - Community	1	1.0475
1DC31	Complex - High	Early - Community	2	1.2046
1EA11	MS Rehab - Low	Early - Community	0	1.0205
1EA21	MS Rehab - Low	Early - Community	1	1.0851
1EA31	MS Rehab - Low	Early - Community	2	1.2422
1EB11	MS Rehab - Medium	Early - Community	0	1.1248
1EB21	MS Rehab - Medium	Early - Community	1	1.1894
1EB31	MS Rehab - Medium	Early - Community	2	1.3465
1EC11	MS Rehab - High	Early - Community	0	1.2862
1EC21	MS Rehab - High	Early - Community	1	1.3507
1EC31	MS Rehab - High	Early - Community	2	1.5078
1FA11	Behavioral Health - Low	Early - Community	0	0.8670
1FA21	Behavioral Health - Low	Early - Community	1	0.9316
1FA31	Behavioral Health - Low	Early - Community	2	1.0887
1FB11	Behavioral Health - Medium	Early - Community	0	1.0251
1FB21	Behavioral Health - Medium	Early - Community	1	1.0896
1FB31	Behavioral Health - Medium	Early - Community	2	1.2468
1FC11	Behavioral Health - High	Early - Community	0	1.1126
1FC21	Behavioral Health - High	Early - Community	1	1.1772
1FC31	Behavioral Health - High	Early - Community	2	1.3343
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8899
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9545
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1116
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0437
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.1082
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2654
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.2086
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2732
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.4303
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9166
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9812
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1383
1HB11	MMTA - Cardiac - Medium	Early - Community	0	1.0412
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.1058
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.2629
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1487
1HC21	MMTA - Cardiac - High	Early - Community	1	1.2133
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3704
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1461
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2107

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3678
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2640
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3286
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4857
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3381
1IC21	MMTA - Endocrine - High	Early - Community	1	1.4027
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5598
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8993
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9639
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1210
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0386
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.1032
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2603
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1294
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1940
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3511
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9176
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9821
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1393
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0392
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.1037
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2608
1KC11	MMTA - Infectious - High	Early - Community	0	1.1710
1KC21	MMTA - Infectious - High	Early - Community	1	1.2355
1KC31	MMTA - Infectious - High	Early - Community	2	1.3926
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9252
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9897
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1469
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0407
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.1052
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2623
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1460
1LC21	MMTA - Respiratory - High	Early - Community	1	1.2105
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3676
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1629
2AA21	MMTA - Other - Low	Early - Institutional	1	1.2274
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3846
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2802
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.3447
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.5018
2AC11	MMTA - Other - High	Early - Institutional	0	1.3915
2AC21	MMTA - Other - High	Early - Institutional	1	1.4560
2AC31	MMTA - Other - High	Early - Institutional	2	1.6132
2BA11	Neuro - Low	Early - Institutional	0	1.3442
2BA21	Neuro - Low	Early - Institutional	1	1.4088
2BA31	Neuro - Low	Early - Institutional	2	1.5659
2BB11	Neuro - Medium	Early - Institutional	0	1.4775
2BB21	Neuro - Medium	Early - Institutional	1	1.5421
2BB31	Neuro - Medium	Early - Institutional	2	1.6992
2BC11	Neuro - High	Early - Institutional	0	1.5994
2BC21	Neuro - High	Early - Institutional	1	1.6640
2BC31	Neuro - High	Early - Institutional	2	1.8211
2CA11	Wound - Low	Early - Institutional	0	1.4589

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
2CA21	Wound - Low	Early - Institutional	1	1.5235
2CA31	Wound - Low	Early - Institutional	2	1.6806
2CB11	Wound - Medium	Early - Institutional	0	1.5782
2CB21	Wound - Medium	Early - Institutional	1	1.6428
2CB31	Wound - Medium	Early - Institutional	2	1.7999
2CC11	Wound - High	Early - Institutional	0	1.6987
2CC21	Wound - High	Early - Institutional	1	1.7632
2CC31	Wound - High	Early - Institutional	2	1.9204
2DA11	Complex - Low	Early - Institutional	0	1.0754
2DA21	Complex - Low	Early - Institutional	1	1.1400
2DA31	Complex - Low	Early - Institutional	2	1.2971
2DB11	Complex - Medium	Early - Institutional	0	1.2162
2DB21	Complex - Medium	Early - Institutional	1	1.2808
2DB31	Complex - Medium	Early - Institutional	2	1.4379
2DC11	Complex - High	Early - Institutional	0	1.1970
2DC21	Complex - High	Early - Institutional	1	1.2616
2DC31	Complex - High	Early - Institutional	2	1.4187
2EA11	MS Rehab - Low	Early - Institutional	0	1.2346
2EA21	MS Rehab - Low	Early - Institutional	1	1.2992
2EA31	MS Rehab - Low	Early - Institutional	2	1.4563
2EB11	MS Rehab - Medium	Early - Institutional	0	1.3389
2EB21	MS Rehab - Medium	Early - Institutional	1	1.4034
2EB31	MS Rehab - Medium	Early - Institutional	2	1.5605
2EC11	MS Rehab - High	Early - Institutional	0	1.5002
2EC21	MS Rehab - High	Early - Institutional	1	1.5648
2EC31	MS Rehab - High	Early - Institutional	2	1.7219
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0811
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1456
2FA31	Behavioral Health - Low	Early - Institutional	2	1.3028
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2392
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.3037
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4608
2FC11	Behavioral Health - High	Early - Institutional	0	1.3267
2FC21	Behavioral Health - High	Early - Institutional	1	1.3913
2FC31	Behavioral Health - High	Early - Institutional	2	1.5484
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.1040
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1686
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3257
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2578
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.3223
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4794
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.4227
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4873
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.6444
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1307
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1953
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3524
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2553
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.3199
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4770
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3628
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.4274
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5845

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.3602
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4248
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.5819
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4781
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5427
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6998
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5522
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.6168
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7739
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1134
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1780
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3351
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2527
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.3173
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4744
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3435
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.4081
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5652
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1317
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1962
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3533
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2532
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.3178
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4749
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3850
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4496
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.6067
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1393
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.2038
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3609
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2547
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.3193
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4764
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3601
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.4246
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5817
3AA11	MMTA - Other - Low	Late - Community	0	0.5540
3AA21	MMTA - Other - Low	Late - Community	1	0.6185
3AA31	MMTA - Other - Low	Late - Community	2	0.7756
3AB11	MMTA - Other - Medium	Late - Community	0	0.6712
3AB21	MMTA - Other - Medium	Late - Community	1	0.7358
3AB31	MMTA - Other - Medium	Late - Community	2	0.8929
3AC11	MMTA - Other - High	Late - Community	0	0.7826
3AC21	MMTA - Other - High	Late - Community	1	0.8471
3AC31	MMTA - Other - High	Late - Community	2	1.0042
3BA11	Neuro - Low	Late - Community	0	0.7353
3BA21	Neuro - Low	Late - Community	1	0.7999
3BA31	Neuro - Low	Late - Community	2	0.9570
3BB11	Neuro - Medium	Late - Community	0	0.8686
3BB21	Neuro - Medium	Late - Community	1	0.9332
3BB31	Neuro - Medium	Late - Community	2	1.0903
3BC11	Neuro - High	Late - Community	0	0.9905
3BC21	Neuro - High	Late - Community	1	1.0551

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
3BC31	Neuro - High	Late - Community	2	1.2122
3CA11	Wound - Low	Late - Community	0	0.8500
3CA21	Wound - Low	Late - Community	1	0.9146
3CA31	Wound - Low	Late - Community	2	1.0717
3CB11	Wound - Medium	Late - Community	0	0.9693
3CB21	Wound - Medium	Late - Community	1	1.0338
3CB31	Wound - Medium	Late - Community	2	1.1910
3CC11	Wound - High	Late - Community	0	1.0898
3CC21	Wound - High	Late - Community	1	1.1543
3CC31	Wound - High	Late - Community	2	1.3114
3DA11	Complex - Low	Late - Community	0	0.4665
3DA21	Complex - Low	Late - Community	1	0.5311
3DA31	Complex - Low	Late - Community	2	0.6882
3DB11	Complex - Medium	Late - Community	0	0.6073
3DB21	Complex - Medium	Late - Community	1	0.6718
3DB31	Complex - Medium	Late - Community	2	0.8290
3DC11	Complex - High	Late - Community	0	0.5881
3DC21	Complex - High	Late - Community	1	0.6527
3DC31	Complex - High	Late - Community	2	0.8098
3EA11	MS Rehab - Low	Late - Community	0	0.6257
3EA21	MS Rehab - Low	Late - Community	1	0.6903
3EA31	MS Rehab - Low	Late - Community	2	0.8474
3EB11	MS Rehab - Medium	Late - Community	0	0.7300
3EB21	MS Rehab - Medium	Late - Community	1	0.7945
3EB31	MS Rehab - Medium	Late - Community	2	0.9516
3EC11	MS Rehab - High	Late - Community	0	0.8913
3EC21	MS Rehab - High	Late - Community	1	0.9559
3EC31	MS Rehab - High	Late - Community	2	1.1130
3FA11	Behavioral Health - Low	Late - Community	0	0.4722
3FA21	Behavioral Health - Low	Late - Community	1	0.5367
3FA31	Behavioral Health - Low	Late - Community	2	0.6938
3FB11	Behavioral Health - Medium	Late - Community	0	0.6303
3FB21	Behavioral Health - Medium	Late - Community	1	0.6948
3FB31	Behavioral Health - Medium	Late - Community	2	0.8519
3FC11	Behavioral Health - High	Late - Community	0	0.7178
3FC21	Behavioral Health - High	Late - Community	1	0.7824
3FC31	Behavioral Health - High	Late - Community	2	0.9395
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.4951
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.5597
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7168
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6488
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7134
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8705
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.8138
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8784
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0355
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5218
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.5864
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7435
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6464
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7110
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8681
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7539

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8185
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9756
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.7513
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.8159
3IA31	MMTA - Endocrine - Low	Late - Community	2	0.9730
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.8692
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9338
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.0909
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9433
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0078
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1650
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5045
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.5691
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7262
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6438
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7084
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8655
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7346
3JC21	MMTA - GI/GU - High	Late - Community	1	0.7991
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9563
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5227
3KA21	MMTA - Infectious - Low	Late - Community	1	0.5873
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7444
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6443
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7089
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8660
3KC11	MMTA - Infectious - High	Late - Community	0	0.7761
3KC21	MMTA - Infectious - High	Late - Community	1	0.8407
3KC31	MMTA - Infectious - High	Late - Community	2	0.9978
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5303
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.5949
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7520
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6458
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7104
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8675
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7511
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8157
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9728
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0690
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1336
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2907
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1863
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2509
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.4080
4AC11	MMTA - Other - High	Late - Institutional	0	1.2976
4AC21	MMTA - Other - High	Late - Institutional	1	1.3622
4AC31	MMTA - Other - High	Late - Institutional	2	1.5193
4BA11	Neuro - Low	Late - Institutional	0	1.2504
4BA21	Neuro – Low	Late - Institutional	1	1.3150
4BA31	Neuro – Low	Late - Institutional	2	1.4721
4BB11	Neuro - Medium	Late - Institutional	0	1.3837
4BB21	Neuro - Medium	Late - Institutional	1	1.4483
4BB31	Neuro - Medium	Late - Institutional	2	1.6054

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
4BC11	Neuro – High	Late - Institutional	0	1.5056
4BC21	Neuro – High	Late - Institutional	1	1.5702
4BC31	Neuro – High	Late - Institutional	2	1.7273
4CA11	Wound – Low	Late - Institutional	0	1.3651
4CA21	Wound – Low	Late - Institutional	1	1.4297
4CA31	Wound – Low	Late - Institutional	2	1.5868
4CB11	Wound - Medium	Late - Institutional	0	1.4844
4CB21	Wound - Medium	Late - Institutional	1	1.5489
4CB31	Wound - Medium	Late - Institutional	2	1.7060
4CC11	Wound – High	Late - Institutional	0	1.6048
4CC21	Wound – High	Late - Institutional	1	1.6694
4CC31	Wound – High	Late - Institutional	2	1.8265
4DA11	Complex – Low	Late - Institutional	0	0.9816
4DA21	Complex – Low	Late - Institutional	1	1.0462
4DA31	Complex – Low	Late - Institutional	2	1.2033
4DB11	Complex - Medium	Late - Institutional	0	1.1224
4DB21	Complex - Medium	Late - Institutional	1	1.1869
4DB31	Complex - Medium	Late - Institutional	2	1.3440
4DC11	Complex – High	Late - Institutional	0	1.1032
4DC21	Complex – High	Late - Institutional	1	1.1678
4DC31	Complex – High	Late - Institutional	2	1.3249
4EA11	MS Rehab – Low	Late - Institutional	0	1.1408
4EA21	MS Rehab – Low	Late - Institutional	1	1.2053
4EA31	MS Rehab – Low	Late - Institutional	2	1.3625
4EB11	MS Rehab - Medium	Late - Institutional	0	1.2450
4EB21	MS Rehab - Medium	Late - Institutional	1	1.3096
4EB31	MS Rehab - Medium	Late - Institutional	2	1.4667
4EC11	MS Rehab – High	Late - Institutional	0	1.4064
4EC21	MS Rehab – High	Late - Institutional	1	1.4710
4EC31	MS Rehab – High	Late - Institutional	2	1.6281
4FA11	Behavioral Health – Low	Late - Institutional	0	0.9872
4FA21	Behavioral Health – Low	Late - Institutional	1	1.0518
4FA31	Behavioral Health – Low	Late - Institutional	2	1.2089
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1453
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.2099
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3670
4FC11	Behavioral Health - High	Late - Institutional	0	1.2329
4FC21	Behavioral Health - High	Late - Institutional	1	1.2974
4FC31	Behavioral Health - High	Late - Institutional	2	1.4546
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0102
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.0748
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2319
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1639
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2285
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3856
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.3289
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3934
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.5506
4HA11	MMTA - Cardiac – Low	Late - Institutional	0	1.0369
4HA21	MMTA - Cardiac – Low	Late - Institutional	1	1.1014
4HA31	MMTA - Cardiac – Low	Late - Institutional	2	1.2586
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1615
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.2260

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Weight
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3832
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2690
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3335
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4907
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.2664
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3309
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.4881
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3843
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4489
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.6060
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4584
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5229
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6800
4JA11	MMTA - GI/GU – Low	Late - Institutional	0	1.0196
4JA21	MMTA - GI/GU – Low	Late - Institutional	1	1.0841
4JA31	MMTA - GI/GU – Low	Late - Institutional	2	1.2413
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1589
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.2234
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3806
4JC11	MMTA - GI/GU – High	Late - Institutional	0	1.2497
4JC21	MMTA - GI/GU – High	Late - Institutional	1	1.3142
4JC31	MMTA - GI/GU – High	Late - Institutional	2	1.4713
4KA11	MMTA - Infectious – Low	Late - Institutional	0	1.0378
4KA21	MMTA - Infectious – Low	Late - Institutional	1	1.1024
4KA31	MMTA - Infectious – Low	Late - Institutional	2	1.2595
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1594
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.2240
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3811
4KC11	MMTA - Infectious – High	Late - Institutional	0	1.2912
4KC21	MMTA - Infectious – High	Late - Institutional	1	1.3558
4KC31	MMTA - Infectious – High	Late - Institutional	2	1.5129
4LA11	MMTA - Respiratory – Low	Late - Institutional	0	1.0454
4LA21	MMTA - Respiratory – Low	Late - Institutional	1	1.1100
4LA31	MMTA - Respiratory – Low	Late - Institutional	2	1.2671
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1609
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2255
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3826
4LC11	MMTA - Respiratory – High	Late - Institutional	0	1.2662
4LC21	MMTA - Respiratory – High	Late - Institutional	1	1.3308
4LC31	MMTA - Respiratory – High	Late - Institutional	2	1.4879

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed from the CCW March 30, 2021.

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To ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the CY 2022 national, standardized 30-day period payment rate. Typically, the case-mix weight budget neutrality factor is calculated using the most recent, complete home health claims data available. However, due to the COVID–19 PHE, we looked at using the previous calendar year's home health claims data (CY 2019) to determine if there were significant differences between utilizing CY 2019 and CY 2020 claims data. We note that CY 2020 is the first year of actual PDGM utilization data, therefore, if we were to use CY 2019 data due to the PHE we would need to simulate 30-day periods from 60-day episodes under the old system. We believe that using CY 2020 utilization data is more appropriate than using CY 2019 utilization data because it is actual PDGM utilization data. The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2022 PDGM case-mix weights

(developed using CY 2020 home health claims data) are applied to CY 2020 utilization (claims) data are equal to total payments when CY 2021 PDGM case-mix weights (developed using CY 2018 home health claims data) are applied to CY 2020 utilization data. This produces a case-mix budget neutrality factor for CY 2022 of 1.0344. For reasons described previously, CY 2020 utilization data was used to calculate the case-mix weight budget neutrality factor because it is the most recent complete data we have at the time of this rulemaking.

We invite comments on the CY 2022 proposed case-mix weights and proposed case-mix weight budget neutrality factor.

4. Proposed CY 2022 Home Health Payment Rate Updates

a. Proposed CY 2022 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for home health be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. In the CY 2019 HH PPS final rule with comment period (83 FR 56425), we finalized a rebasing of the home health market basket to reflect 2016 cost report data. As such, based on the rebased 2016-based home health market basket, we finalized that the labor share is 76.1 percent and the non-labor share is 23.9 percent. A detailed description of how we rebased the HHA market basket is available in the CY 2019 HH PPS final rule with comment period (83 FR 56425 through 56436).

Section 1895(b)(3)(B) of the Act requires that in CY 2015 and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), and CY 2020 (under section 53110 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123, enacted February 9, 2018)), the market basket percentage under the HHA prospective payment system, as described in section 1895(b)(3)(B) of the Act, be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (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) is the agency that publishes the official measure of private nonfarm business MFP. Please visit *http://www.bls.gov/mfp,* to obtain the BLS historical published MFP data.

The proposed home health update percentage for CY 2022 is based on the estimated home health market basket update, specified at section 1895(b)(3)(B)(iii) of the Act, of 2.4 percent (based on IHS Global Inc.'s first-quarter 2021 forecast with historical data through fourth-quarter 2020). The estimated CY 2022 home health market basket update of 2.4 percent is then reduced by a productivity adjustment, as mandated by the section 3401 of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), currently estimated to be 0.6 percentage point for CY 2022. In effect, the proposed home health payment update percentage for CY 2022 is a 1.8 percent increase. Section 1895(b)(3)(B)(v) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2022, the home health payment update would be −0.2 percent (1.8 percent minus 2 percentage points). If more recent data becomes available after the publication of this proposed rule and before the publication of the final rule (for example, more recent estimates of the home health market basket update and productivity adjustment), we would use such data, if appropriate, to determine the home health payment update percentage for CY 2022 in the final rule.

b. CY 2022 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home payments. We propose to continue this practice for CY 2022, as we continue to believe that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data is appropriate and reasonable for the HH PPS.

In the FY 2021 HH PPS final rule (85 FR 70298), we finalized the proposal to adopt the revised OMB delineations with a 5 percent cap on wage index decreases, where the estimated reduction in a geographic area's wage index would be capped at 5 percent in CY 2021 only and no cap would be applied to wage index decreases for the second year (CY 2022). Therefore, we propose to use the FY 2022 pre-floor, pre-reclassified hospital wage index with no 5 percent cap on decreases as the CY 2022 wage adjustment to the labor portion of the HH PPS rates. For CY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017, and before October 1, 2018 (FY 2018 cost report data). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2022 HH PPS wage index, we propose to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we propose to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we propose to continue to use the most recent wage index previously available for that area. The most recent wage index previously available for rural Puerto Rico is 0.4047. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. For CY 2022, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). The CY 2022 wage index value for Hinesville, GA is 0.8557.

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the

delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted OMB's area delineations using a 1-year transition.

On August 15, 2017, OMB issued Bulletin No. 17–01 in which it announced that one Micropolitan Statistical Area, Twin Falls, Idaho, now qualifies as a Metropolitan Statistical Area. The new CBSA (46300) comprises the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho. The CY 2022 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8757. Bulletin No. 17–01 is available 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. A copy of OMB Bulletin No. 18–04 may be obtained at: *https://www.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-metropolitan-statistical-areas.pdf.*

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 *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 Are and changes to New England City and Town Area (NECTA) delineations. In the CY 2021 HH PPS final rule (85 FR 70298) we stated that if appropriate, we would propose any updates from OMB Bulletin No. 20–01 in future rulemaking. 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 CY 2022. Specifically, the updates consisted of changes to NECTA delineations and the redesignation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare wage index does not utilize NECTA definitions, and, as most recently discussed in the CY 2021 HH PPS final rule (85 FR 70298) 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 CY 2022 as a result of adopting these OMB updates. In other words, these OMB updates would not affect any geographic areas for purposes of the wage index calculation for CY 2022.

The proposed CY 2022 wage index is available on the CMS website at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

c. CY 2022 Annual Payment Update

(1) Background

The HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020.

As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2019 HH PPS final rule with comment period (83 FR 56435), we finalized rebasing the home health market basket to reflect 2016 Medicare cost report data. We also finalized a revision to the labor share to reflect the 2016-based home health market basket compensation (Wages and Salaries plus Benefits) cost weight. We finalized that for CY 2019 and subsequent years, the labor share would be 76.1 percent and the non-labor share would be 23.9 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2021:

- Multiply the national, standardized 30-day period rate by the patient's applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (76.1 percent) and a non-labor portion (23.9 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period payment amount, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health payment update, minus 2 percentage points. Any reduction of the percentage change would apply only to the calendar year involved and would not be considered in computing the prospective payment amount for a subsequent calendar year.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A LUPA is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A PEP adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

(2) CY 2022 National, Standardized 30-Day Period Payment Amount

CMS provided preliminary monitoring data for the first year of PDGM and presented a repricing method to determine the differences between assumed and actual behavior changes and the impact of such on estimated aggregate expenditures, as discussed in Section III.B of this

proposed rule. For CY 2022, we are not proposing to make any additional permanent or temporary adjustments to the national, standardized 30-day period payment in this proposed rule in accordance with section 1895(b)(3)(D) of the Act.

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget-neutral manner. To determine the CY 2022 national, standardized 30-day period payment rate, we apply a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor and the home health payment update percentage discussed in Section III.C.2 of this proposed rule. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we apply a case-mix weights budget neutrality factor to the CY 2021 national, standardized 30-day period payment rate. The proposed case-mix weights budget neutrality factor for CY 2022 is 1.0344.

Additionally, we also apply a wage index budget neutrality to ensure that wage index updates and revisions are implemented in a budget neutral manner. Typically, the wage index budget neutrality factor is calculated using the most recent, complete home health claims data available. However, due to the COVID–19 PHE, we looked at using the previous calendar year's home health claims data (CY 2019) to determine if there were significant differences between utilizing 2019 and 2020 claims data. Our analysis showed that there is only a small difference between the wage index budget neutrality factors calculated using CY 2019 and CY 2020 home health claims data. Therefore, we have decided to continue our practice of using the most recent, complete home health claims data available; that is we are using CY 2020 claims data for the CY 2022 payment rate updates.

To calculate the wage index budget neutrality factor, we simulated total payments using CY 2020 home health claims utilization data for non-LUPA 30-day periods using the proposed CY 2022 wage index and compared it to our simulation of total payments for non-LUPA 30-day periods using the CY 2021 wage index. By dividing the total payments for non-LUPA 30-day periods using the CY 2022 wage index by the total payments for non-LUPA 30-day periods using the CY 2021 wage index, we obtain a wage index budget neutrality factor of 1.0013. We would apply the wage index budget neutrality factor of 1.0013 to the 30-day period payment rate.

Next, we would update the 30-day period payment rate by the CY 2022 home health payment update percentage of 1.8 percent. The CY 2022 national, standardized 30-day period payment rate is calculated in Table 19.

TABLE 19: CY 2022 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2021 National Standardized 30-Day Period Payment	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update	CY 2022 National, Standardized 30-Day Period Payment
$1,901.12	1.0390	1.0013	1.018	$2,013.43

The CY 2022 national, standardized 30-day period payment rate for a HHA that does not submit the required quality data is updated by the CY 2022 home health payment update of 1.8 percent minus 2 percentage points and is shown in Table 20.

TABLE 20: CY 2022 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2021 National Standardized 30-Day Period Payment	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update Minus 2 Percentage Points	CY 2022 National, Standardized 30-Day Period Payment
$1,901.12	1.0390	1.0013	0.998	$1,973.88

(3) CY 2022 National Per-Visit Rates for 30-Day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2022 national per-visit rates, we started with the CY 2021 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-

visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA 30-day periods of care using the CY 2022 wage index and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2021 wage index. By dividing the total payments for LUPA 30-day periods of care using the CY 2022 wage index by the total payments for LUPA 30-day periods of care using the CY 2021 wage index, we obtained a wage index budget neutrality factor of 1.0014. We apply the wage index budget neutrality factor in order to calculate the CY 2022 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weights budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2022 home health payment update percentage of 1.8 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2022 national per-visit rates for HHAs that submit the required quality data are updated by the CY 2022 home health payment update percentage of 1.8 percent and are shown in Table 21.

TABLE 21: CY 2022 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2021 Per-Visit Payment	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update	CY 2022 Per-Visit Payment
Home Health Aide	$69.11	X 1.0014	X 1.018	$70.45
Medical Social Services	$244.64	X 1.0014	X 1.018	$249.39
Occupational Therapy	$167.98	X 1.0014	X 1.018	$171.24
Physical Therapy	$166.83	X 1.0014	X 1.018	$170.07
Skilled Nursing	$152.63	X 1.0014	X 1.018	$155.59
Speech-Language Pathology	$181.34	X 1.0014	X 1.018	$184.86

The CY 2022 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2020 home health payment update percentage of 1.8 percent minus 2 percentage points and are shown in Table 22.

TABLE 22: CY 2022 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2021 Per-Visit Rates	Wage Index Budget Neutrality Factor	CY 2022 HH Payment Update Minus 2 Percentage Points	CY 2022 Per-Visit Rates
Home Health Aide	$69.11	X 1.0014	X 0.998	$69.07
Medical Social Services	$244.64	X 1.0014	X 0.998	$244.49
Occupational Therapy	$167.98	X 1.0014	X 0.998	$167.88
Physical Therapy	$166.83	X 1.0014	X 0.998	$166.73
Skilled Nursing	$152.63	X 1.0014	X 0.998	$152.54
Speech- Language Pathology	$181.34	X 1.0014	X 0.998	$181.23

We are reminding stakeholders of the policies finalized in the CY 2020 HH PPS final rule with comment period (84 FR 60544) and the implementation of a new one-time Notice of Admission (NOA) process starting in CY 2022. In that final rule, we finalized the lowering of the up-front payment made in response to Requests for Anticipated Payment (RAPs) to zero percent for all 30-day periods of care beginning on or after January 1, 2021 (84 FR 60544). For CY 2021, all HHAs (both existing and newly-enrolled HHAs) were required to submit a RAP at the beginning of each 30-day period in order to establish the home health period of care in the common working file and also to trigger the consolidated billing edits. With the removal of the upfront RAP payment for CY 2021, we relaxed the required information for submitting the RAP for CY 2021 and also stated that the information required for submitting an NOA for CYs 2022 and beyond would mirror that of the RAP in CY 2021. Starting in CY 2022, HHAs will submit a one-time NOA that establishes the home health period of care and covers all contiguous 30-day periods of care until the individual is discharged from Medicare home health services. Also, for the one-time NOA for CYs 2022 and

beyond, we finalized a payment reduction if the HHA does not submit the NOA for CYs 2022 and beyond within 5 calendar days from the start of care. That is, if an HHA fails to submit a timely NOA for CYs 2022 and beyond, the reduction in payment amount would be equal to a one-thirtieth reduction to the wage and case-mix adjusted 30-day period payment amount for each day from the home health start of care date until the date the HHA submitted the NOA. In other words, the one-thirtieth reduction would be to the 30-day period adjusted payment amount, including any outlier payment, that the HHA otherwise would have received absent any reduction. For LUPA 30-day periods of care in which an HHA fails to submit a timely NOA, no LUPA payments would be made for days that fall within the period of care prior to the submission of the NOA. We stated that these days would be a provider liability, the payment reduction could not exceed the total payment of the claim, and that the provider may not bill the beneficiary for these days.

We remind stakeholders that for purposes of determining if an NOA is timely-filed, the NOA must be submitted within 5 calendar days after the start of care for the first 30-day period of care. For example, if the start of care for the first 30-day period is January 1, 2022, the NOA would be considered timely-filed if it is submitted on or before January 6, 2022.

Example

1/1/2022 = Day 0 (start of the first 30-day period of care)

1/6/2022 = Day 5 (An NOA submitted on or before this date would be considered ''timely-filed''.)

1/7/2022 and after = Day 6 and beyond (An NOA submitted on and after this date will trigger the penalty.) In the event that the NOA is not timely-filed, the penalty is calculated from the first day of that 30-day period (in the example, the penalty calculation would begin with the start of care date of January 1, 2022, counting as the first day of the penalty) until the date of the submission of the NOA.

Also, in the CY 2020 HH PPS final rule with comment period (84 FR 60478), we finalized exceptions to the timely filing consequences of the NOA requirements at § 484.205(j)(4). Specifically, we finalized that CMS may waive the consequences of failure to submit a timely-filed NOA if it is determined that a circumstance encountered by a home health agency is exceptional and qualifies for waiver of the consequence. As finalized in the CY 2020 HH PPS final rule with comment period and as set forth in regulation at § 484.205(j)(4), an exceptional circumstance may be due to, but is not limited to the following:

- Fires, floods, earthquakes, or similar unusual events that inflict extensive damage to the home health agency's ability to operate.
- A CMS or Medicare contractor systems issue that is beyond the control of the home health agency.
- A newly Medicare-certified home health agency that is notified of that certification after the Medicare certification date, or which is awaiting its user ID from its Medicare contractor.
- Other situations determined by CMS to be beyond the control of the home health agency.

If an HHA believes that there is a circumstance that may qualify for an exception, the HHA must fully document and furnish any requested documentation to their MAC for a determination of exception.

For more in-depth information regarding the finalized policies associated with the new one-time NOA process, we refer readers to the CY 2020 HH PPS final rule with comment period (84 FR 60544) as well as the regulations at § 484.205(j).

(4) LUPA Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As stated in the CY 2008 HH PPS final rule, the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount.

In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-visit payment amount for the first skilled nursing, physical therapy, or speech-language pathology visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM. For example, using the proposed CY 2022 per-visit payment rates for those HHAs that submit the required quality data, for LUPA periods that occur as the only period or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit would be $287.06 (1.8451 multiplied by $155.58), subject to area wage adjustment.

(5) Proposed Occupational Therapy LUPA Add-On Factor

In order to implement Division CC, section 115, of CAA 2021, we are proposing conforming changes to regulations at §§ 484.55(a)(2) and 484.55(b)(3) that were revised to allow OTs to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but includes either PT or SLP. Because of this change, we are proposing to establish a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled occupational therapy visit in LUPA periods that occurs as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. Currently, there are no sufficient data regarding the average excess of minutes for the first visit in LUPA periods where the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we propose to utilize the PT LUPA add-on factor of 1.6700 as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts. We believe that the similarity in the per-visit payment rates for both PT and OT make the PT LUPA add-on factor the most appropriate proxy. We welcome comments on this proposal.

d. Rural Add-On Payments for CY 2022

(1) Background

Section 421(a) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173) required, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or

after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent. Section 5201 of the Deficit Reduction Act of 2003 (DRA) (Pub. L. 108–171) amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016. Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018.

Section 50208(a) of the BBA of 2018 amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2019.

(2) Rural Add-On Payments for CYs 2019 Through CY 2022

Section 50208(a)(1)(D) of the BBA of 2018 added a new subsection (b) to section 421 of the MMA to provide rural add-on payments for episodes or visits ending during CYs 2019 through 2022. It also mandated implementation of a new methodology for applying those payments. Unlike previous rural add-ons, which were applied to all rural areas uniformly, the extension provided varying add-on amounts depending on the rural county (or equivalent area) classification by classifying each rural county (or equivalent area) into one of three distinct categories: (1) Rural counties and equivalent areas in the highest quartile of all counties and equivalent areas based on the number of Medicare home health episodes furnished per 100 individuals who are entitled to, or enrolled for, benefits under Part A of Medicare or enrolled for benefits under Part B of Medicare only, but not enrolled in a Medicare Advantage plan under Part C of Medicare (the ''High utilization'' category); (2) rural counties and equivalent areas with a population density of 6 individuals or fewer per square mile of land area and are not included in the ''High utilization'' category (the ''Low population density'' category); and (3) rural counties and equivalent areas not in either the ''High utilization'' or ''Low population density'' categories (the ''All other'' category).

In the CY 2019 HH PPS final rule with comment period (83 FR 56443), CMS finalized policies for the rural add-on payments for CY 2019 through CY 2022, in accordance with section 50208 of the BBA of 2018. The CY 2019 HH PPS proposed rule (83 FR 32373) described the provisions of the rural add-on payments, the methodology for applying the new payments, and outlined how we categorized rural counties (or equivalent areas) based on claims data, the Medicare Beneficiary Summary File and Census data. The data used to categorize each county or equivalent area is available in the Downloads section associated with the publication of this rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html.* In addition, an Excel file containing the rural county or equivalent area name, their Federal Information Processing Standards (FIPS) State and county codes, and their designation into one of the three rural add-on categories is available for download.

The HH PRICER module, located within CMS' claims processing system, will increase the CY 2022 30-day base payment rates, described in section III.C.3. of this proposed rule, by the appropriate rural add-on percentage prior to applying any case-mix and wage index adjustments. The CY 2019 through CY 2022 rural add-on percentages outlined in law are shown in Table 23.

TABLE 23: HOME HEALTH PPS RURAL ADD-ON PERCENTAGES, CYs 2019-2022

Category	CY 2019	CY 2020	CY 2021	CY 2022
High utilization	1.5%	0.5%	None	None
Low population density	4.0%	3.0%	2.0%	1.0%
All other	3.0%	2.0%	1.0%	None

e. Proposed Payments for High-Cost Outliers Under the HH PPS

(1) Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS and the previous unit of payment (that is, 60-day episodes), outlier payments were made for 60-day episodes whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or PEP adjustment defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier

threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act and revised the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10-percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold; and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

In the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, the per unit rates used to estimate an episode's cost were updated by the home health update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We will continue to monitor the visit length by discipline as more recent data becomes available, and may propose to update the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-day periods of care in CY 2020. Given that CY 2020 was the first year of the PDGM and the change to a 30-day unit of payment, we finalized to maintain the same FDL ratio of 0.56 in CY 2021 as we did not have sufficient CY 2020 data at the time of CY 2021 rulemaking to proposed a change to the FDL ratio for CY 2021.

(2) Fixed Dollar Loss (FDL) Ratio for CY 2022

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of periods that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must be lower.

The FDL ratio and the loss-sharing ratio are selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio, which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount. Using CY 2020 claims data (as of March 30, 2021), and given the statutory requirement that total outlier payments does not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are proposing a FDL ratio of 0.41 for CY 2022.

6. Conforming Regulations Text Changes Regarding Allowed Practitioners

As stated in the May 2020 COVID–19 interim final rule with comment period (85 FR 27550), we amended the regulations at parts 409, 424, and 484 to implement section 3708 of the CARES Act. This included defining a nurse practitioner (NP), a clinical nurse specialist (CNS), and a physician's assistant (PA) (as such qualifications are defined at §§ 410.74 through 410.76) as ''allowed practitioners'' (85 FR 27572). This means that in addition to a physician, as defined at section 1861(r) of the Act, an allowed practitioner may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. Additionally, we amended the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by a physician or an allowed non-physician practitioner (NPP), as set forth in § 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying allowed practitioner may be different from the provider physician or allowed practitioner that performed the face-to-face encounter. These regulations text changes are not time

limited to the period of the COVID–19 PHE.

When implementing plan of care changes in the CY 2021 HH PPS final rule (85 FR 70298), the term ''allowed practitioner'' was inadvertently deleted from the regulation text at § 409.43. Therefore, in this proposed rule we are proposing conforming regulations text changes at § 409.43 to reflect that allowed practitioners, in addition to physicians, may establish and periodically review the plan of care.

III. Home Health Value-Based Purchasing (HHVBP) Model

A. Proposal To Expand the HHVBP Model Nationwide

1. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the CMS Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing Model (original Model) in nine States on January 1, 2016. The last year of data collection for the original Model ended on December 31, 2020. The original Model design leveraged the successes of and lessons learned from other value-based purchasing programs and demonstrations to shift from volume-based payments to a Model designed to promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original Model were to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, we selected nine States for inclusion in the original HHVBP Model, representing each geographic area across the nation. All Medicare-certified home health agencies (HHAs) providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington were required to compete in the original Model. We stated that requiring all Medicare-certified HHAs in the selected States to participate in the Model ensures that there is no selection bias, participants are representative of HHAs nationally, and there would be sufficient participation to generate meaningful results.

The original Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust the Medicare payment amounts under section 1895(b) of the Act based on the competing HHAs' performance on applicable quality measures. Under the original Model, CMS adjusts fee-for-service payments to Medicare-certified HHAs based on each HHA's performance on a set of quality measures in a given performance year measured against a baseline year and relative to peers in its State. The maximum payment adjustment percentage increased incrementally, upward or downward, over the course of the original Model in the following manner: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year, which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS),[11] completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and claims-based measures; and (2) three New Measures for which points were achieved for reporting data. Payment adjustments for a given year are based on the TPS calculated for performance two years' prior; for example, the CY 2018 payment adjustments were based on CY 2016 performance.

In the CY 2017 HH PPS final rule (81 FR 76741 through 76752), CY 2018 HH PPS final rule (83 FR 51701 through 51706), and CY 2019 HH PPS final rule (83 FR 56527 through 56547), we finalized changes to the original Model. Some of those changes included adding and removing measures from the applicable measure set, revising our methodology for calculating benchmarks and achievement thresholds at the State level, creating an appeals process for recalculation requests, and revising our methodologies for weighting measures and assigning improvement points.

On January 8, 2021, we announced that the HHVBP Model had been certified for expansion nationwide,[12] as well as our intent to expand the Model through notice and comment rulemaking beginning no sooner than CY 2022. The original Model has resulted in an average 4.6 percent improvement in home health agencies' quality scores as well as average annual savings of $141 million to Medicare.[13]

As described in this proposed rule, we are proposing to expand the HHVBP Model (expanded Model/Model expansion) to all 50 States, the District of Columbia and the territories starting in CY 2022. We are proposing to codify HHVBP Model expansion policies at §§ 484.340; 484.345; 484.350; 484.355; 484.360; 484.365; 484.370; and 484.375, as discussed in more detail in the sections that follow.

2. Requirements for Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through notice and comment rulemaking, the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of benefits.

- *Improved Quality of Care without Increased Spending:* As observed in the Third Annual Evaluation Report,[14] the HHVBP Model resulted in improved quality of care (for example, consistently increasing TPS scores) and a reduction in Medicare expenditures through three performance years of the HHVBP Model (CYs 2016 to 2018). The HHVBP Model's intervention has led to savings without evidence of adverse risks. The evaluation also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) visits, resulting in reductions in inpatient and SNF spending. Based on these findings, the Secretary determined that expansion of the HHVBP Model would reduce spending and improve the quality of care.

- *Impact on Medicare Spending:* The CMS Chief Actuary has certified that expansion of the HHVBP Model would

[11] OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

[12] *https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.*

[13] *https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.*

[14] The HHVBP Third Annual Evaluation Report is available at *https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.*

produce Medicare savings if expanded to all States.[15]

• *No Alteration in Coverage or Provision of Benefits:* The HHVBP Model did not make any changes to coverage or provision of benefits for Medicare beneficiaries. Therefore, the Secretary has determined that expansion of the HHVBP Model would not deny or limit the coverage or provision of Medicare benefits for Medicare beneficiaries.

Consistent with our statutory authority, we would continue to test and evaluate the expanded HHVBP Model. In the future, we would assess whether the expanded implementation of HHVBP is continuing to reduce Medicare spending without reducing quality of care or to improve the quality of patient care without increasing spending, and could modify the expanded HHVBP Model as appropriate through rulemaking.

3. Overview

The proposed HHVBP Model expansion presents an opportunity to improve the quality of care furnished to Medicare beneficiaries nationwide through payment incentives to HHAs. If finalized, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories would be required to participate in the expanded HHVBP Model beginning January 1, 2022. These HHAs would compete on value based on an array of quality measures related to the care that HHAs furnish.

The proposed Model expansion would be tested under section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. The Secretary is not issuing any waivers of the fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act or any other Medicare or Medicaid fraud and abuse laws for this Model expansion at this time. In addition, CMS has determined that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(hh)(9)(ii)) will not be available to protect remuneration exchanged pursuant to any financial arrangements or patient incentives permitted under the Model. Thus, notwithstanding any other provisions of this proposed rule, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories must comply with all applicable fraud and abuse laws and regulations.

We are proposing to use the section 1115A(d)(1) of the Act waiver authority to apply a reduction or increase of up to 5 percent to Medicare payments to Medicare-certified HHAs delivering care to beneficiaries in the 50 States, District of Columbia and the territories, depending on the HHA's performance on specified quality measures relative to its peers. Specifically, the expanded HHVBP Model proposes to utilize the section 1115A(d)(1) of the Act waiver authority to adjust the Medicare payment amounts under section 1895(b) of the Act. In accordance with the authority granted to the Secretary in section 1115A(d)(1) of the Act, we would waive section 1895(b)(4) of the Act only to the extent necessary to adjust payment amounts to reflect the value-based payment adjustments under this proposed expanded Model for Medicare-certified HHAs in the 50 States, District of Columbia and the territories. We may make changes to the payment adjustment percentage through rulemaking in future years of the expansion, as additional evaluation data from the HHVBP expanded Model become available, and we learn about performance within the Model under the expansion. The evaluation of the expanded Model would use a time series type approach to examine the outcomes of interest (cost or utilization) over time prior to the start of the intervention and follow that outcome after the start of the expansion.

a. Overview of Timing and Scope

As noted, we are proposing to begin the expanded HHVBP Model on January 1, 2022. Under this proposal, CY 2022 would be the first performance year and CY 2024 would be the first payment year, with payment adjustments in CY 2024 based on an HHA's performance in CY 2022. Performance year means the calendar year during which data are collected for the purpose of calculating a competing HHA's performance on applicable quality measures. Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

The proposed expanded Model would apply to all Medicare-certified HHAs in the 50 States, District of Columbia and the territories, which means that all Medicare-certified HHAs that provide services in the 50 States, District of Columbia and the territories would be required to compete in the expanded Model. We are proposing to codify this requirement at § 484.350. We are proposing to define a 'competing HHA' within the scope of the proposed expanded HHVBP Model as an HHA that has a current Medicare certification and is being paid by CMS for home health care services. We propose that all HHAs certified for participation in Medicare before January 1, 2021 would have their CY 2022 performance assessed and would be eligible for a CY 2024 payment adjustment. We propose to base participation in the expanded Model on CMS Certification Numbers (CCNs), meaning that the Total Performance Score as discussed further in section III.A.7.a. of this proposed rule and payment adjustment would be calculated based on an HHA's CCN.[16]

b. Overview of the Payment Adjustment

As proposed, the distribution of payment adjustments would be based on quality performance, as measured by both achievement and improvement, across a proposed set of quality measures constructed to minimize burden as much as possible and improve care. Competing HHAs that demonstrate they can deliver higher quality of care in a given performance year measured against a baseline year relative to peers nationwide (as defined by larger- versus smaller-volume cohorts based upon their unique beneficiary count in the prior calendar year), could have their HH PPS claims final payment amount adjusted higher than the amount that otherwise would be paid. Competing HHAs that do not perform as well as other competing HHAs in the same volume-based cohort might have their HH PPS claims final payment amount reduced and those competing HHAs that perform similarly to others in the same volume-based cohort might have no payment adjustment. This operational concept is similar in practice to what is used in the Hospital Value-Based Purchasing (HVBP) Program (76 FR 26531).

We expect that the risk of having payments adjusted in this manner would provide an incentive among all competing HHAs to provide significantly better quality through improved planning, coordination, and management of care. Under the expanded duration and scope of this Model, we would continue to examine

[15] The full CMS Actuary Report is available at *https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.*

[16] HHAs are required to report OASIS data and any other quality measures by its own unique CMS Certification Number (CCN) as defined under Title 42, Chapter IV, Subchapter G, § 484.20 Available at URL *http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr484_main_02.tpl.*

whether the proposed adjustments to the Medicare payment amounts that would otherwise be made to competing HHAs would result in statistically significant improvements in the quality of care being delivered to Medicare beneficiaries, as well as reductions in Medicare spending. The degree of the payment adjustment would be dependent on the level of quality achieved or improved from the baseline year, with the highest upward performance adjustments going to competing HHAs with the highest overall level of performance based on either achievement or improvement in quality. The size of a competing HHA's payment adjustment for each year under the expanded Model would be dependent upon that HHA's performance with respect to the applicable performance year relative to other competing HHAs in the same volume-based cohort and relative to its own performance during the baseline year. Details are discussed in sections III.A.4, III.A.5, and III.A.7.a of this proposed rule.

In addition, at § 484.345 we propose to add the following definitions:

- Achievement threshold
- Applicable measure
- Applicable percent
- Baseline year
- Benchmark
- Competing home health agency
- Home health prospective payment system
- Improvement threshold
- Larger-volume cohort
- Linear exchange function
- Nationwide
- Payment adjustment
- Payment year
- Performance year
- Smaller-volume cohort
- Total Performance Score

4. Defining Cohorts for Benchmarking and Competition

Under the original HHVBP Model, we grouped HHAs into cohorts by State for setting benchmarks and achievement thresholds and by both State and smaller- versus larger-volume HHAs when determining the cohorts used for competing for payment adjustments, in accordance with § 484.330. For the nationwide expansion of the HHVBP Model, we are proposing to redefine the cohort structure to account for States, territories, and the District of Columbia with smaller numbers of HHAs, while also allowing for the use of volume-based cohorts in determining benchmarks, achievement thresholds, and payment adjustments.

a. Proposed Smaller- and Larger-Volume Cohorts

As discussed further in this section, we believe that separating smaller- and larger-volume HHAs into cohorts under the expanded Model would facilitate like comparisons by allowing for the majority of HHAs to receive benchmarks and compete for payment against other HHAs of similar size and based on the same set of measures. As under the original HHVBP Model, we propose to align the larger-volume cohort with the group of competing HHAs that administers the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey, in accordance with the HH QRP regulations concerning the HHCAHPS survey in § 484.245(b), and we propose to align the Model's smaller-volume HHA cohort with the group of HHAs that are exempt from submitting the HHCAHPS survey under HH QRP under § 484.245(b)(1)(iii)(A). Under the expanded HHVBP Model, we would not alter the HHCAHPS survey current scoring methodology or the participation requirements in any way. Details on HHCAHPS survey scoring methodology are available at: *https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials.*[17]

The HH QRP requires, in part, that an HHA submit HHCAHPS survey data to CMS. An HHA that has fewer than 60 eligible unique HHCAHPS survey patients must annually submit their total HHCAHPS survey patient count to CMS to be exempt from the HHCAHPS survey reporting requirements for a calendar year. As under the original HHVBP Model, we propose to align with this HHCAHPS survey reporting requirement by defining the larger-volume cohort as those HHAs that are required to submit an HHCAHPS survey in the performance year. As under the original Model, we also propose to set an HHCAHPS survey measure minimum of at least 40 completed HHCAHPS surveys in the performance year for those HHAs to receive a score on the HHCAHPS survey measure, as reflected in proposed §§ 484.345 and 484.360. Accordingly, because smaller-volume HHAs are less likely to be assessed on the HHCAHPS survey measure, which would account for 30 percent of the overall performance score in the expanded Model, we believe that separating smaller- and larger-volume HHAs into distinct cohorts would allow for the majority of HHAs to compete against other HHAs of similar size and based on the same set of measures.

b. Proposed Cohorts for the Model Expansion

As discussed, we believe that applying separate larger- and smaller-volume cohorts within the expanded HHVBP Model would group HHAs that are of similar size and are more likely to receive scores on the same set of measures for purposes of setting benchmarks and achievement thresholds and determining payment adjustments. However, a valid cohort must have a sufficient number of HHAs to—(1) create a robust distribution of Total Performance Scores, which allows meaningful and reasonable translation into payment adjustments using the linear exchange function (LEF);[18] and (2) set stable, reliable benchmarks and achievement thresholds that are not heavily skewed by outliers. The LEF is designed so that the majority of the payment adjustment values fall closer to the median and a smaller percentage of HHAs receive adjustments at the higher and lower ends of the distribution. However, when only a small number of HHAs fall within a cohort, one HHA's outlier TPS could skew the payment adjustments and deviate from the intended design of the LEF payment methodology. As a result, a key consideration in defining the cohorts is ensuring sufficient HHA counts within each cohort.

Under the original Model, CMS applied a minimum of eight HHAs for any size cohort, such that a smaller-volume cohort must have a minimum of eight HHAs in order for the HHAs in that cohort to be compared only against each other, and not against the HHAs in the larger-volume cohort (81 FR 76742). This policy was based on an analysis of the minimum number of HHAs needed in a smaller-volume cohort in order to insulate that cohort from the effect of outliers. Expanding the HHVBP Model beyond the nine mid- to large-sized States included in the original Model requires us to re-examine these cohort definitions because, certain territories and the District of Columbia would fall short of the original Model's minimum of 8 HHAs to compose their own cohort even where the volume-based cohorts are combined. This was not an issue in the original Model because the nine selected States are relatively populous as compared to the smaller States,

[17] Detailed scoring information is contained in the Protocols and Guidelines manual posted on the HHCAHPS website and available at *https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials.*

[18] The Linear Exchange Function (LEF) is used to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. For a more detailed description, please see section III.A.8. of this proposed rule.

territories, and the District of Columbia that would be included in the expanded Model. Based on CY 2019 Home Health Compare Star Ratings, we evaluated the viability of smaller- and larger-volume cohorts, as defined previously, for each of the 55 States, territories, and the District of Columbia. Based on our analysis, of the 110 potential cohorts based on both State and HHA volume for the expanded HHVBP Model, 46 of the 110 potential cohorts had too few HHAs to reliably meet the original Model minimum of 8 HHAs, after accounting for the risk of attrition from the expanded Model. Under this approach, for 42 of these 46 States and territories, the smaller-volume cohorts would need to be combined with the larger-volume cohorts in their States and territories, while 3 territories and the District of Columbia would need to be combined with other States or territories since they do not meet the 8 HHA minimum after consolidating the volume-based cohorts. See Table 24 for the counts of HHAs in each of the potential cohorts, if we were to apply separate State- and volume-based cohorts for each State, territory, and the District of Columbia under the expanded Model.

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TABLE 24: HHA COUNTS IN STATE/TERRITORY/DISTRICT OF COLUMBIA- AND VOLUME-BASED COHORTS BASED ON CY 2019 HOME HEALTH CARE COMPARE DATA

State	Large HHAs	Small HHAs	All HHAs	State	Large HHAs	Small HHAs	All HHAs
AK	12	1	13	MT	22	2	24
AL	114	1	115	NC	152	4	156
AR	90	2	92	ND	12	-	12
AZ	106	2	108	NE	40	8	48
CA	993	76	1,069	NH	20	1	21
CO	105	4	109	NJ	42	-	42
CT	74	-	74	NM	58	4	62
DC*	7	-	7	NV	97	8	105
DE	12	-	12	NY	105	-	105
FL	677	54	731	OH	287	10	297
GA	99	-	99	OK	183	10	193
GU*	4	-	4	OR	43	1	44
HI	14	-	14	PA	229	12	241
IA	94	7	101	PR	33	-	33
ID	42	1	43	RI	18	-	18
IL	399	64	463	SC	63	-	63
IN	138	11	149	SD	19	4	23
KS	84	5	89	TN	112	1	113
KY	90	-	90	TX	982	97	1,079
LA	167	-	167	UT	68	6	74
MA	127	5	132	VA	187	6	193
MD	49	2	51	VI*	1	-	1
ME	19	1	20	VT	10	-	10
MI	322	54	376	WA	57	-	57
MN	97	9	106	WI	73	-	73
MO	123	9	132	WV	50	1	51
MP*	2	-	2	WY	16	2	18
MS	45	-	45	**All**	**7,084**	**485**	**7,569**

*These territories and the District of Columbia fall short of the original HHVBP Model's minimum of 8 HHAs to compose their own cohort even where the volume-based cohorts are combined.

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As noted, under the original HHVBP Model, a minimum of eight HHAs is required for each size cohort. For the expanded HHVBP Model, we are proposing to establish cohorts prospectively and with sufficient HHA counts to prevent the need to combine multiple cohorts retrospectively. We propose to provide HHAs with their

applicable benchmarks and achievement thresholds prior to the start of or during the performance year so that they can be used to set performance targets to guide HHAs' quality improvement projects. To reliably define cohorts prospectively and to avoid regrouping multiple States, territories, or the District of Columbia into a single cohort retrospectively based solely on their lower HHA counts, we estimate that a minimum of 20 HHAs in each cohort would be necessary to ensure that attrition and variation in episode counts do not lead to insufficient HHA counts at the end of the performance year. Based on the data set forth in Table 24, 61 out of the 110 potential cohorts would have fewer than 20 HHAs in a size-based cohort, and 11 out of those potential cohorts would not meet the 20 HHA minimum after combining the size-based cohorts.

To allow for a sufficient number of HHAs in each volume-based cohort, for purposes of setting benchmarks and achievement thresholds and determining payment adjustments, we are proposing to use cohorts based on all HHAs nationwide, rather than by State as under the original Model. Referencing the CY 2019 data in Table 24, under this approach, 7,084 HHAs would fall within the larger-volume cohort and 485 HHAs fall within the smaller-volume cohort. These HHA counts would provide a sufficiently large number of values in each cohort to allow ranking of HHA performance scores and payment adjustment percentages across the range of −5 percent to +5 percent. Further, our analysis found that many of the smaller-volume HHAs would not receive a score on the HHCAHPS survey measures, which are proposed to account for 30percent of the overall TPS, while most of the larger-volume cohort HHAs would be scored on the full set of applicable measures. Accordingly, and as previously discussed, we believe the volume-based cohorts would allow for competition among HHAs across similar measures. Using nationwide rather than State/territory-based cohorts in performance comparisons would also be consistent with the Skilled Nursing Facility and Hospital VBP Programs, in addition to the Home Health Compare Star Ratings. Finally, this option would be the least operationally complex to implement.

For the reasons discussed, we believe the use of nationwide smaller- and larger-volume-based cohorts would allow for appropriate groupings of HHAs under the expanded Model while also providing sufficient numbers of HHAs in each cohort for purposes of setting stable and reliable benchmarks and achievement thresholds and allowing for a robust distribution of payment adjustments. However, we also considered an alternative approach of using State/territory-based cohorts, without volume-based groupings. Applying the State, territory, and District of Columbia-level cohorts, we found that 11 of the 55 potential cohorts would have fewer than 20 HHAs based on the CY 2019 Home Health Star Ratings data. As noted, we do not believe this would allow for a sufficient number of HHAs to develop prospective benchmarks and achievement thresholds. While one approach would be to exclude any States, territories, or the District of Columbia from the expanded Model for years in which there are fewer than 20 HHAs in the cohort, we believe such a policy would be inconsistent with the goal of including all eligible HHAs nationwide in the Model. Another option would be to consolidate those States, territories, and the District of Columbia with less than 20 HHAs in the cohort, and to calculate benchmarks, achievement thresholds, and payment adjustments based on that consolidated grouping of HHAs. We note that while slight differences do exist between quality measure scores based on geographic location, we do not believe that codifying these small differences into long-term performance standards is necessary to appropriately determine payment adjustments under the expanded Model.

We are proposing to establish nationwide volume-based cohorts for the expanded HHVBP Model, such that HHAs nationwide would compete within either the larger-volume cohort or the smaller-volume cohort. We propose to codify this policy at § 484.370, and to codify the proposed definitions of smaller-volume cohort and larger-volume cohort at § 484.345. Under this proposal, HHAs currently participating in the original HHVBP Model would no longer compete within just their State. We are also requesting comment on the alternative approach of applying State/territory-based cohorts only, without volume-based cohorts, which we may finalize after consideration of comments received.

We seek public comment on these proposals.

5. Proposed Payment Adjustment Percentage and Performance Assessment and Payment Adjustment Periods

a. Proposed Payment Adjustment

Under the original Model, the payment adjustment ranges from a minimum of 3 percent in 2018 to maximum of 8 percent in 2022. For the expanded Model, we are proposing that the maximum payment adjustment, upward or downward, would be 5 percent. We believe that beginning the expansion with a 5 percent maximum payment adjustment would strike a balance between the 3 percent maximum adjustment that applied for CY 2018, the first payment year of the original HHVBP Model, and the 7 percent maximum adjustment currently in place for CY 2021. As proposed in section III.A.3.a. of this proposed rule, the first payment year of the expanded HHVBP Model would be CY 2024 (January 1, 2024 through December 31, 2024), with payment adjustments based on performance in CY 2022 (January 1, 2022 through December 31, 2022). We may consider changes to the proposed 5 percent maximum payment adjustment percentage through rulemaking in future years of the expansion, as additional evaluation data from the original Model and expansion become available. We note that the CMS Actuary certification was based on evaluation of the Model when the maximum payment adjustment was 3 percent. However, in their certification memo, they indicated they believe the Model would result in savings at higher payment adjustment amounts as well.

We seek public comment on the proposed payment adjustment percentage.

b. Proposed Baseline Year

(1) General

For the expanded HHVBP Model, due to the potentially de-stabilizing effects of the COVID–19 public health emergency (PHE) on quality measure data in CY 2020, we propose that the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance year/CY 2024 payment year and subsequent years. The data from this baseline year would provide a basis from which each respective HHA's performance would be measured for purposes of calculating achievement and improvement points under the expanded Model. We may propose to update the baseline year for subsequent years of the expanded Model through future rulemaking. We would also propose the applicable baseline year for any additional quality measures that may be added to the measure set for the expanded HHVBP Model through future rulemaking.

We seek public comment on the proposed baseline year for the expanded Model.

(2) New HHAs

As noted, we are generally proposing that for the expanded Model, the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance year/CY 2024 payment year and subsequent years. For new HHAs, specifically those HHAs that are certified by Medicare on or after January 1, 2019, we are proposing that the baseline year under the expanded Model would be the HHA's first full CY of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year would be CY 2021. Furthermore, we propose that new HHAs would begin competing under the expanded HHVBP Model in the first full calendar year following the full calendar year baseline year. For example, and as previously discussed, we are proposing that all HHAs certified for participation in Medicare before January 1, 2021 would have their CY 2022 performance assessed and would be eligible for a CY 2024 payment adjustment. For HHAs certified on January 1, 2020 through December 31, 2020, the baseline year would be CY 2021, the first full CY of services beginning after the date of Medicare certification. For those HHAs certified on January 1, 2019 through December 31, 2019, the baseline year would also be CY 2021, rather than CY 2020 (the first full CY of services beginning after the date of Medicare certification), due to the potentially destabilizing effects of the PHE on quality measure data in CY 2020. For an HHA certified by Medicare on January 1, 2021 through December 31, 2021, for example, the first full calendar year of services that would establish the HHA's baseline year would be CY 2022. The HHA's first performance year would be CY 2023 and the HHA's first payment year, based on CY 2023 performance, would be CY 2025. Table 25 shows the proposed HHA baseline, performance and payment years based on the HHA's Medicare-certification date through December 31, 2021.

TABLE 25: PROPOSED HHA BASELINE, PERFORMANCE AND PAYMENT YEAR BASED ON MEDICARE-CERTIFICATION DATE THROUGH DECEMBER 31, 2021

Medicare-certification Date	Baseline Year	Performance Year	Payment Year
Prior to January 1, 2019	2019	2022	2024
On January 1, 2019 - December 31, 2019	2021	2022	2024
On January 1, 2020 – December 31, 2020	2021	2022	2024
On January 1, 2021 – December 31, 2021	2022	2023	2025

We also propose to codify our proposal on new HHAs at § 484.350. We seek public comment on this proposal.

6. Quality Measures

a. General Considerations Used for the Selection of Quality Measures for the Expanded HHVBP Model

We plan to apply, to the extent possible, principles from CMS' Meaningful Measures Initiative in selecting the applicable measures as defined at § 484.345 to be included in the Model expansion. A central driver of the proposed applicable measure set is to have a broad, high impact on care delivery and support priorities to improve health outcomes, quality, safety, efficiency, and experience of care for patients. To frame the selection process, we also considered the domains of the CMS Quality Strategy [19] that maps to the six National Quality Strategy (NQS) [20] priority areas: Clinical quality of care; Care coordination; Population/community health; efficiency and cost reduction; safety; and, Patient and caregiver-centered experience.

We believe that Medicare-certified HHAs should be evaluated using measures designed to encompass multiple NQS domains, and provide future flexibility to incorporate and study newly developed measures over time. Additionally, so that measures for the expanded HHVBP Model take a more holistic view of the patient beyond a particular disease, functional status, State or care setting, we would prioritize outcome measures that have the potential to follow patients across multiple settings, reflect a multi-faceted approach, and foster the intersection of health care delivery and population health.

The proposed expanded Model measures mostly align with those under the HH QRP. However, we intend to consider new measures for inclusion in subsequent years of the expanded HHVBP Model through future rulemaking. We may consider adding new measures to the expanded HHVBP Model measure set that address gaps within the NQS domains or the home health service line and are good indicators of home health quality of care. When available, NQF endorsed measures would be used. The expanded Model's section 1115A of the Act authority also affords the opportunity to study other measures, such as, measures developed in other care settings or new to the home health industry, should CMS identify such measures. A key consideration behind this approach is to use measures that are readily available, and, in subsequent Model years, augment the applicable measure set with innovative measures that have the potential to be impactful and fill critical measure gap areas. This approach to quality measure selection aims to balance the burden of collecting data with the inclusion of new and important measures. We would carefully consider the potential burden on HHAs to report the measure data that is not already collected through existing quality measure data reporting systems and reiterate that we would propose any new measures through future rulemaking.

[19] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[20] For NQF endorsed measures see The NQF Quality Positioning System available at *http://www.qualityforum.org/QPS.* For non-NQF measures using OASIS see links for data tables related to OASIS measures at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.*

b. Proposed Measure Set Beginning With the CY 2022 Performance Year/CY 2024 Payment Year and Subsequent Years

We propose that the initial applicable measure set for the expanded HHVBP Model for the CY 2022 performance year focus on patient outcome and functional status, utilization, and patient experience. The proposed measures were also used under the original Model (83 FR 56533). However, we note that no ''New Measures'' as defined in the original Model (80 FR 68674) are being proposed for data collection under the expanded Model beginning with the CY 2022 performance year given there was sufficient data collected on the ''New Measures'' under the original Model for analysis of the appropriateness for use in the home health setting. We note that any future additional measures proposed for the expanded HHVBP Model would not be considered ''New Measures'' as used in the original Model.

Beginning with the CY 2022 performance year/CY 2024 payment year and for subsequent years, we propose the following measures as detailed in Table 26 for inclusion in the expanded Model. The measure set also includes outcome measures, which illustrate the end result of care delivered to HHA patients and address an important quality aim for HHA patients. We believe the proposed measure set under the expanded HHVBP Model, where most measures currently align with HH QRP measures, supports enhancing quality because of the value-based incentives provided under the expanded Model. Further, we believe that the expanded Model measure set, as proposed, includes an array of measures that would capture the care that HHAs furnish and incentivize quality improvement. The measures in the proposed measure set are divided into measure categories based on their data source as indicated in Table 26: Claims-based, OASIS-based, and the HHCAHPS survey-based. We note that the HHCAHPS survey-based measure has five individual components. The term ''applicable measure'' applies to each of the five components for which a competing HHA has submitted a minimum of 40 completed HHCAHPS surveys (This is discussed in more detail in sections III.A.4.a., III.A.7.c., and III.A.7.d. of this proposed rule). That is, each component counts as one applicable measure towards the five measure minimum that is required for an HHA to receive a Total Performance Score (TPS) (this is discussed in more detail in section III.A.7.d of this proposed rule).

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TABLE 26: PROPOSED MEASURE SET FOR THE EXPANDED HHVBP MODEL (Beginning with the CY 2022 Performance Year/CY 2024 Payment Year and Subsequent Years*)

NQS Domains	Measure Full Title/Short Form Name (if applicable)	Measure Type	Measure Steward	Identifier	Data Source	Numerator	Denominator	Link to Measure Specifications
OASIS-based								
Clinical Quality of Care	Improvement in Dyspnea/Dyspnea	Outcome	NA	NA	OASIS (M1400)	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
Communication & Care Coordination	Discharged to Community	Outcome	NA	NA	OASIS (M2420)	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
Patient Safety	Improvement in Management of Oral Medications/Oral Medication	Outcome	CMS	NQF 0176	OASIS (M2020)	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
Patient and Family Engagement	Total Normalized Composite Change in Mobility*/TNC Mobility	Composite Outcome	NA	NA	OASIS (M1840) (M1850) (M1860)	The total normalized change in mobility functioning across three OASIS items (toilet transferring, bed transferring, and ambulation/locomotion)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.	https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf

Table 27 provides more granular detail on the elements of the Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey measure.

NQS Domains	Measure Full Title/Short Form Name (if applicable)	Measure Type	Measure Steward	Identifier	Data Source	Numerator	Denominator	Link to Measure Specifications
Patient and Family Engagement	Total Normalized Composite Change in Self-Care**/TNC Self-Care	Composite Outcome	NA	NA	OASIS (M1800) (M1810) (M1820) (M1830) (M1845) (M1870)	The total normalized change in self-care functioning across six OASIS items (grooming, bathing, upper & lower body dressing, toilet hygiene, and eating)	A prediction model is computed at the episode level. The predicted value for the HHA and the national value of the predicted values are calculated and are used to calculate the risk-adjusted rate for the HHA, which is calculated using this formula: HHA Risk Adjusted = HHA Observed + National Predicted – HHA Predicted.	https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf
Claims-based								
Efficiency & Cost Reduction	Acute Care Hospitalization During the First 60 Days of Home Health Use/ACH	Outcome	CMS	NQF 0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
Efficiency & Cost Reduction	Emergency Department Use without Hospitalization During the First 60 Days of Home Health/ED Use	Outcome	CMS	NQF 0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.	https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-Outcome-Measures-Table-OASIS-D-11-2018c.pdf
HHCAHPS Survey-based								
Patient & Caregiver-Centered Experience	Home Health Consumer Assessment Healthcare Providers and Systems (HHCAHPS) Survey	Outcome	CMS	NQF 0517	CAHPS	Survey-based. HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure	Survey-based. HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure	Links provided in Table 28

*Because the Total Normalized Composite Change in Mobility measure is a composite measure rather than simply an outcome measure, the terms "Numerator" and "Denominator" do not apply.
**Because the Total Normalized Composite Change in Self-Care measure is a composite measure rather than simply an outcome measure, the terms "Numerator" and "Denominator" do not apply.

TABLE 27: HHCAHPS SURVEY MEASURE COMPONENTS AND COMPONENT QUESTIONS

HHCAHPS Survey-based* Component Name/ Short Name and Component Question	Type	NQF ID	Data Source	Link to Component Specs/Response Categories
Care of Patients/Professional Care	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2062
Q9. In the last 2 months of care, how often did home health providers from this agency seem informed and up-to-date about all the care or treatment you got at home?				Never, Sometimes, Usually, Always
Q16. In the last 2 months of care, how often did home health providers from this agency treat you as gently as possible?				Never, Sometimes, Usually, Always
Q19. In the last 2 months of care, how often did home health providers from this agency treat you with courtesy and respect?				Never, Sometimes, Usually, Always
Q24. In the last 2 months of care, did you have any problems with the care you got through this agency?				Yes, No
Communications between Providers and Patients/Communication	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2580
Q2. When you first started getting home health care from this agency, did someone from the agency tell you what care and services you would get?				Yes, No
Q15. In the past 2 months of care, how often did home health providers from this agency keep you informed about when they would arrive at your home?				Never, Sometimes, Usually, Always
Q17. In the past 2 months of care, how often did home health providers from this agency explain things in a way that was easy to understand?				Never, Sometimes, Usually, Always
Q18. In the past 2 months of care, how often did home health providers from this agency listen carefully to you?				Never, Sometimes, Usually, Always
Q22. In the past 2 months of care, when you contacted this agency's office did you get the help or advice you needed?				Yes, No
Q23. When you contacted this agency's office, how long did it take for you to get the help or advice you needed?				Same day; 1 to 5 days; 6 to 14 days; More than 14 days
Specific Care Issues/Team Discussion	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2582
Q3. When you first started getting home health care from this agency, did someone from the agency talk with you about how to set up your home so you can move around safely?				Yes, No
Q4. When you started getting home health care from this agency, did someone from the agency talk with you about all the prescription medicines you are taking?				Yes, No
Q5. When you started getting home health care from this agency, did someone from the agency ask to see all the prescription medicines you were taking?				Yes, No
Q10. In the past 2 months of care, did you and a home health provider from this agency talk about pain?				Yes, No
Q12. In the past 2 months of care, did home health providers from this agency talk with you about the **purpose** for taking your new or changed prescription medicines?				Yes, No
Q13. In the last 2 months of care, did home health providers from this agency talk with you about **when** to take these medicines?				Yes, No
Q14. In the last 2 months of care, did home health providers from this agency talk with you about the **important side effects** of these medicines?				Yes, No

Overall rating of home health care/Overall Rating	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2581
Q20. What number would you use to rate your care from this agency's home health providers?				Use a rating scale (0-10) (0 is worst, 10 is best)
Willingness to recommend the agency/Willing to Recommend	Outcome	0517	CAHPS	https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=2583
Q25. Would you recommend this agency to your family or friends if they needed home health care?				Definitely no; Probably no; Probably yes; Definitely yes

*The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure. Detailed scoring information is contained in the Protocols and Guidelines manual posted on the HHCAHPS website and available at https://homehelathcahps.org/Survey-and-Protocols/Survey-Materials.

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(1) Additional Background on the Total Normalized Composite Measures

The proposed measure set includes two composite measures: Total Normalized Composite (TNC) Self-Care and TNC Mobility, which were included in the original HHVBP Model measure set in CY 2019, as finalized in the CY 2019 HH PPS final rule (83 FR 56529 through 56535). The methodology for these measures take into account patients who may not have goals for improvement.

The proposed TNC Self-Care measure computes the magnitude of change, either positive or negative, based on a normalized amount of possible change on each of six OASIS-based quality outcomes. These six outcomes are as follows:

- Improvement in Grooming (M1800)
- Improvement in Upper Body Dressing (M1810)
- Improvement in Lower Body Dressing (M1820)
- Improvement in Bathing (M1830)
- Improvement in Toileting Hygiene (M1845)
- Improvement in Eating (M1870)

The TNC Mobility measure computes the magnitude of change, either positive or negative, based on the normalized amount of possible change on each of three OASIS-based quality outcomes. These three outcomes are as follows:

- Improvement in Toilet Transferring (M1840)
- Improvement in Bed Transferring (M1850)
- Improvement in Ambulation/Locomotion (M1860)

For each TNC measure, we calculate at the episode level and then aggregate to the home health agency level using a five-step process: Steps 1 to 3 calculate the normalized change values for each applicable OASIS item at the episode level. Steps 4 and 5 aggregate these values to the agency level. As composite measures, the TNC Self-Care and TNC Mobility measures reflect multiple OASIS items, so there are no numerators or denominators for these two measures. A detailed description of the five steps can be found at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf.* We expect that HHAs already focus on improvement in such areas not just because such items are included in the OASIS, but because self-care and mobility are areas of great importance to patients and families. Improvement in such areas may allow beneficiaries to remain in the home setting (versus an institution) and contribute to beneficiaries' quality of life. The risk adjustment methodology for these two measures recalibrates the expectations for improvement by including risk factors for a wide variety of beneficiary-level factors, including age, risk for hospitalization, condition categories, living arrangements and caregivers available, pain, cognitive function, baseline functional status, and others. For instance, a beneficiary with impaired cognition would not be expected to improve in self-care as much as a beneficiary with intact cognition. In effect, the self-care improvement score would shift up slightly for a beneficiary with impaired cognition relative to a beneficiary without cognitive impairment to account for the difference in expectations. Both TNC measures' computations can be found at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20computing%20the%20hhvbp%20composite%20measures.pdf* and the technical specifications can be found at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hhvbp%20technical%20specification%20resource%20for%20composite%20outcome%20measures_4.pdf.* Additional information on the predictive modeling and methodology for the composite measures can be found in the CY 2019 HH PPS final rule (83 FR 56529 through 56535).

We note that we had considered the inclusion of stabilization measures which are measures that identify all patients whose function has not declined, including both those who have improved or stayed the same in the original HHVBP Model's measure set and refer readers to the CY 2016 HH PPS final rule (80 FR 68669 through 68670) and the CY 2019 HH PPS final rule (83 FR 56529 through 56535). In the CY 2016 final rule, we explained that we considered using some of the stabilization measures for the original Model and found that the average HHA stabilization measure scores ranged from 94 to 96 percent and, with average rates of nearly 100 percent. We do not believe these high measure scores would allow for meaningful comparisons between competing-HHAs on the quality of care delivered. We acknowledge that skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition. However, we believe that the two proposed TNC measures represent a new direction in how quality of patient care is measured in home health as patients who receive care from an HHA may have functional limitations and may be at risk for further decline in function because of limited mobility and ambulation.

(2) Additional Background on the Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey Measure

The Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey (HHCAHPS) survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. The HHCAHPS survey specifically presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1) Produce comparable data on the patient's perspective that allows objective and meaningful comparisons between HHAs on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.[21]

We note that the HHCAHPS survey is also part of the HH QRP's data submission requirements, which are codified for that program at 42 CFR 484.245(b). As proposed, expanded HHVBP Model participants would not need to submit separate HHCAHPS survey measure data already submitted as a requirement under HH QRP, because the requirements as proposed for the expanded Model are aligned with those currently under HH QRP. For more details about the HHCAHPS Survey, please see *https://homehealthcahps.org/.*

We invite public comment on our proposed measure set.

c. Measure Modifications

During the expanded Model, we would monitor the quality measures for lessons learned and address any needed

[21] *https://homehealthcahps.org/General-Information/About-Home-Health-Care-CAHPS-Survey.*

adjustments or modifications to the expanded Model measure set.

(1) Proposed Substantive vs. Non-Substantive Changes Policy

Updates to measures may result from various sources including, for example, measure stewards and owners, new clinical guidelines, a public health emergency, CMS-identified, a technical expert panel (TEP), or NQF. How we incorporate those updates would depend on whether the changes are substantive or non-substantive.

With respect to what constitutes a substantive versus a non-substantive change, we expect to make this determination on a measure-by-measure basis. Examples of such non-substantive changes might include updated diagnosis or procedure codes, medication updates for categories of medications, broadening of age ranges, and changes to exclusions for a measure. We believe that non-substantive changes may include updates to measures based upon changes to guidelines upon which the measures are based. These types of maintenance changes are distinct from more substantive changes to measures that result in what can be considered new or different measures, and that they do not trigger the same agency obligations under the Administrative Procedure Act.

We propose that, in the event that an update to a measure is necessary in a manner that we consider to not substantially change the nature of the measure, we will use a sub-regulatory process to incorporate those updates to the measure specifications. Specifically, we would revise the information that is posted on the CMS website so that it clearly identifies the updates and provides links to where additional information on the updates can be found. In addition, we would provide sufficient lead time for HHAs to implement the changes where changes to the data collection systems would be necessary.

We are also proposing to use notice and comment rulemaking to adopt changes to measures that we consider to substantially change the nature of the measure. Examples of changes that we might consider to be substantive would be those in which the changes are so significant that the measure is no longer the same measure, or when a standard of performance assessed by a measure becomes more stringent, such as changes in acceptable timing of medication, procedure/process, test administration, or expansion of the measure to a new setting. We believe that our proposal adequately balances the need to incorporate changes to measures used in the expanded HHVBP Model in the most expeditious manner possible, while preserving the public's ability to comment on updates to measures that so fundamentally change a measure that it is no longer the same measure originally adopted. We note that CMS adopted a similar policy for the HH QRP in the CY 2015 HH PPS final rule (79 FR 66079 through 66081).

We invite public comment on our proposal.

d. Measure Removals

The measure set used for the expanded Model would be subject to change including the removal of measures during subsequent years. In this proposed rule, for greater transparency, we propose factors we would consider in proposing to remove a measure as well as a policy for when immediate suspension is necessary.

(1) Proposed Removal Factors

We propose to generally use the below removal factors when considering a quality measure for removal for use in the expanded HHVBP Model:

- Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made (that is, topped out). To determine ''topped-out'' criteria, we will calculate the top distribution of HHA performance on each measure, and if the 75th and 90th percentiles are statistically indistinguishable, we will consider the measure topped-out.
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- Factor 5. A measure that is more proximal in time to desired patient outcomes for the particular topic is available.
- Factor 6. A measure that is more strongly associated with desired patient outcomes for the particular topic is available.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

With respect to Factor 8, under our Meaningful Measures Initiative, we are engaging in efforts to ensure that the expanded HHVBP Model measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe that these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the expanded HHVBP Model. We have identified several different types of costs, including, but not limited to the following:

- Provider and clinician information collection burden and burden associated with the submitting/reporting of quality measures to CMS.
- The provider and clinician cost associated with complying with other HH programmatic requirements.
- The provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs.
- The cost to CMS associated with the program oversight of the measure, including measure maintenance and public display.
- The provider and clinician cost associated with compliance with other Federal and State regulations (if applicable).

For example, it may be of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports the expanded HHVBP Model goals (for example, no longer provides incentives for better quality care with greater efficiency). It may also be costly for HHAs to track confidential feedback and publicly reported information on a measure where we use the measure in more than one initiative, model, or program. We may also have to expend resources to maintain the specifications for the measure, including the tools needed to collect, validate, analyze, and publicly report the measure data.

When these costs outweigh the evidence supporting the continued use of a measure in the expanded HHVBP Model, we believe that it may be appropriate to remove the measure from the Model. Although we recognize that the expanded HHVBP Model is to encourage HHAs to improve beneficiary outcomes by incentivizing health care providers, we also recognize that this can have limited utility where, for example, the data is of limited use because it is not meaningful. In these cases, removing the measure from the expanded HHVBP Model may better accommodate the costs of expansion administration and compliance without sacrificing improved health outcomes.

We propose that we would remove measures based on Factor 8 on a case-by-case basis. For example, we may decide to retain a measure that is burdensome for HHAs to report if we conclude that the benefit to beneficiaries is so high that it justifies the reporting burden. Our goal is to move the expanded HHVBP Model forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We believe that even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality. We would apply these factors on a case-by-case basis.

In addition, as noted previously, the authority to expand the HHVBP Model affords the opportunity to study new measures that are not currently collected or submitted to CMS by HHAs. Because of this, there may be other unforeseen reasons that necessitates the removal of a measure that is not currently captured in one of the factors noted previously. In such cases, we would still use notice and comment rulemaking to remove the measure and provide the reasons for doing so.

We seek public comment on our proposals.

(2) Proposed Measure Suspension Policy

Removal of an expanded HHVBP Model measure would take place through notice and comment rulemaking as proposed above unless we determine that a measure is causing concern for patient safety or harm. We propose that in the case of an expanded HHVBP Model measure for which there is a reason to believe that the continued collection raises possible patient safety concerns, we would promptly suspend the measure and immediately notify HHAs and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings. We would then propose to remove or modify the measure as appropriate during the next rulemaking cycle.

We request public comment on our proposal.

e. Future Topics or Measure Considerations

(1) Consideration To Align or Remove Measures With the HH QRP

We note that in section IV.C. of this proposed rule, the CMS proposes to replace the Acute Care Hospitalization During the First 60 Days of Home Health (ACH) measure and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (ED Use) measure with the Home Health Within-Stay Potentially Preventable Hospitalization (PPH) for the HH QRP measure beginning with the CY 2023 under the in the HH QRP. We note that while both the ACH and ED Use measure are being proposed for removal under the HH QRP, these measures are being proposed for inclusion in the expanded HHVBP Model beginning with the CY 2022 performance year. We seek public comment on whether we should instead align the expanded HHVBP Model with the proposed changes for HH QRP by proposing to remove the same two measures from the expanded Model in a future year. We note that any measure removals would be proposed in future notice and comment rulemaking.

We request public feedback on this future consideration.

(2) Health Equity Considerations for the Expanded HHVBP Model

In section VIII.B. of this proposed rule, we include a Request for Information on ways to close the health equity gap in post-acute care quality reporting programs, including the HH QRP. We refer readers to that section for discussion of our current health equity efforts in quality measurement and reporting and potential modifications we have considered or may consider in the future. However, in recognition of persistent health disparities and the importance of closing the health equity gap, we request public comment on ways in which we could incorporate health equity goals and principles into the expanded HHVBP Model. Specifically, we seek comment on the challenges unique to value-based purchasing frameworks in terms of promoting health equity, and ways in which we could incorporate health equity goals into the expanded HHVBP Model.

f. Measure Submissions—Form, Manner, and Timing

We propose at § 484.355 that home health agencies will be evaluated using a set of quality measures, and data submitted under the expanded Model must be submitted in the form and manner, and at a time, specified by CMS. Additional details regarding specific types of measures are discussed later in this section.

As noted previously, the expanded HHVBP Model measures in the proposed measure set beginning with the CY 2022 performance year would use data currently already reported by HHAs. The proposed measure set includes OASIS [22] measures, submitted through the OASIS assessment, which is required to be submitted as part of the Medicare Conditions of Participation (CoPs), the HHCAHPS survey measure, which is required under the HH QRP, and claims-based measures, which are calculated by CMS based on claims data HHAs already submit for purposes of payment. In many cases, measures from the expanded HHVBP Model overlap with those in the HH QRP, and HHAs would only need to submit data once to fulfill requirements of both. However, as described in section III.6.a. of this proposed rule, in the future we may propose new measures that may not otherwise already be collected or submitted by HHAs.

We request comment on our proposal.

(1) Form, Manner, and Timing of OASIS Measure Data

CMS home health regulations, codified at § 484.250(a), require HHAs to submit to CMS OASIS data as is necessary for CMS to administer payment rate methodologies. All HHAs must electronically report all Outcome and Assessment Information Set (OASIS) [23] data collected in accordance with § 484.55(b), (c) and (d) in order to meet the Medicare CoPs, and as a condition for payment at § 484.205(c). The OASIS assessment contains data items developed to measure patient outcomes and improve home health care. HHAs submit the OASIS assessment in the internet Quality Improvement Evaluation System (iQIES) (*https://iqies.cms.gov/*). We note that the CoPs require OASIS accuracy and that monitoring and reviewing is done by CMS surveyors (§ 488.68(c)). It is important to note that to calculate quality measures from OASIS data, there must be a complete quality episode, which requires both a Start of Care (initial assessment) or Resumption of Care OASIS assessment and a Transfer or Discharge OASIS

[22] For detailed information on OASIS see the official CMS web resource available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.*

[23] For detailed information on OASIS see the official CMS web resource available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits.*

assessment. Failure to submit sufficient OASIS assessments to allow calculation of quality measures, including transfer and discharge assessments, is a failure to comply with the CoPs § 484.225(i). HHAs do not need to submit OASIS data for patients who are excluded from the OASIS submission requirements Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies final rule (70 FR 76202) where we excluded patients—

- Receiving only non-skilled services;
- For whom neither Medicare nor Medicaid is paying for HH care (patients receiving care under a Medicare or Medicaid Managed Care Plan are not excluded from the OASIS reporting requirement);
- Receiving pre- or post-partum services; or
- Under the age of 18 years.

We are proposing that HHAs participating in the expanded HHVBP Model would also be required to submit OASIS data according to the requirements of the CMS home health regulations codified at § 484.250(a) and OASIS data described in § 484.55(b), (c) and (d). If finalized, this would mean that HHAs would not be required to submit additional data through OASIS specifically for the expanded Model compared to what is already required for COPs, and there would be no additional burden. We note that this proposed requirement also aligns with requirements under the Home Health QRP (82 FR 4578).

For the expanded Model, we propose that the underlying source data used to calculate an OASIS quality measure score beginning with the CY 2022 performance year comes from 12 months of OASIS assessment data from the applicable performance period via iQIES. The data extracted from iQIES for all OASIS measures, besides the two TNC measures, are aggregated to the monthly level for each HHA, separated by observed and predicted values used to calculate risk adjusted values. For the two TNC measures, we propose to use raw OASIS assessments to calculate applicable measure scores consistent with how we developed these measures.

We request comment on our proposals.

(2) Form, Manner, and Timing of HHCAHPS Survey Measure Data

Under the HH QRP, HHAs are required to contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS on its behalf (42 CFR 484.245(b)(1)(iii)(B)) among other requirements.

For purposes of the expanded HHVBP Model, we propose similar requirements that align with the HH QRP HHCAHPS survey measure data reporting requirement at 484.245(b)(1)(iii). Specifically, under the expanded Model we propose that—

- HHAs must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf;
- CMS approves an HHCAHPS survey vendor if the applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years;
- A ''survey of individuals'' is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes;
- No organization, firm, or business that owns, operates, or provides staffing for an HHA is permitted to administer its own HHCAHPS Survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations are not be approved by CMS as HHCAHPS survey vendors;
- Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors' company locations; and
- Patient count exemption: HHAs that have fewer than 60 eligible unique HHCAHPS survey patients must annually submit to CMS their total HHCAHPS survey patient count to CMS to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

A CMS contractor provides the agency with the HHCAHPS survey measure score aggregated to the 12-months of data for the applicable performance period.

The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org* or contact the HHCAHPS help desk *hhcahps@rti.org.* Again, we reiterate that these proposed requirements would align with those under the HH QRP and would not add additional burden to HHAs.

We also propose to codify these proposals at § 484.355(a)(1)(ii).

We request public comment on these proposals.

(3) Form, Manner, and Timing of Claims-Based Measures

Claims-based measures are derived from claims data submitted to CMS for payment purposes. Claims-based utilization measures provide information related to the use of health care services (for example, hospitals, emergency departments, etc.) resulting from a change in patient health status. We calculate claims-based measures based on claims data submitted to CMS for payment purposes. Therefore, HHAs do not need to submit additional information for purposes of calculating claims-based measures.

We propose that the underlying source data for claims-based measures is 12 months of claims data during the applicable performance period for purposes of payment under the expanded Model.

We request comment on our proposal.

(4) Proposed Data Reporting for Monitoring and Evaluation of the Expanded HHVBP Model

Consistent with requirements under the original HHVBP Model at§ 484.315(c), we propose that competing HHAs under the expanded HHVBP Model would be required to collect and report information to CMS necessary for the purposes of monitoring and evaluating this model as required by statute.[24] We also propose to codify this at § 484.355(b).

We seek public comment on these proposals.

(5) Proposal To Use Authority Under Section 1115A(d)(1) of the Act To Waive Provisions Outlined in 1890A(a)(1) and (3) Through (6) of the Act

In section III.A.11. of this proposed rule, we propose a public reporting framework for the expanded HHVBP Model that would include annual public reporting of quality performance data. This data includes national benchmarks and achievement thresholds, HHA-level performance results for HHAs that qualify for an annual payment adjustment that includes applicable quality measure scores, Total Performance Scores and percentile rankings, improvement thresholds, and payment adjustment percentages. Section 1890A(a)(1) through (6) of the Act set forth requirements regarding the pre-rulemaking process for the selection of quality and efficiency measures described in section 1890(b)(7)(B) of the Act, including quality and efficiency measures used in reporting performance information to the public. We are proposing to utilize the Center for Medicare and Medicaid Innovation's waiver authority under section 1115A(d)(1) of the Act to waive the steps outlined in section 1890A(a)(1) and (3) through (6) of the Act that

[24] See 1115A(b)(4) of the Act (42 U.S.C. 1315a).

pertain to the pre-rulemaking process for publicly reporting performance information to the extent necessary to test the proposed expanded Model.

Section 1115A(d)(1) of the Act allows the Secretary to waive certain statutory requirements ''as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).'' Specifically, we propose to waive section1890A(a)(1) and (3) through (6) of the Act which pertains to: Convening multi-stakeholder groups to provide input to the Secretary on the use of quality and efficiency measures; transmitting the input from the multi-stakeholder groups to the Secretary; consideration of the input by the Secretary from the multi-stakeholder groups; publication in the **Federal Register** of the rationale on the quality and efficiency measures not endorsed for use; and, conduct an impact assessment every three years on the use of such measures.

We note that we are not proposing to waive step 2 of the 6 steps in the pre-rulemaking process. Step 2 pertains to the public availability of measures considered for selection. Section 1890A(a)(2) of the Act specifically applies to quality and efficiency measures under Title XVIII, whereas the expanded model would be implemented under section 1115A of the Act, which is in Title XI.

We are proposing to waive the steps outlined in sections 1890A(a)(1) and (3) through (6) of the Act to the extent necessary in order to allow maximum flexibility to continue to test the expanded HHVBP Model under authority of section 1115A of the Act. The timeline associated with completing the steps described by these provisions would impede our ability to support testing new measures in a timely fashion, as well as testing new ways to incentivize quality performance in the home health setting and a new way to pay for home health care services. We plan to continue to seek input from a Technical Expert Panel (TEP) and to monitor quality measure performance to inform potential measure set changes under the expanded Model. Waiving the five steps noted previously for the expanded HHVBP Model would allow for a more flexible timeline with more timely evaluation and monitoring of quality performance and results.

Flexibility in timing to adjust the quality measure set and/or methodology to respond to unexpected events and trends in home health care, as well as to respond timely to any stakeholder concerns, is critical to the success of the HHVBP Model expansion. The ongoing uncertainty levied by the COVID–19 pandemic, and similar events that may come in the future, requires us to maintain responsiveness to anomalies in the quality measure data. These challenges may require the flexibility to timely implement changes to ensure that measure sets continue to appropriately assess performance in light of external factors. In addition, trends in market consolidation and small business policies in the home health care industry could require certain adjustments to measure methodology, that is, minimum volume requirements, or require adjustment to the applicability of measures. The home health care sector is also becoming a more important source of care for beneficiaries who prefer to age in the community, rather than in an institution. This trend, in addition to the national shift in beneficiary demographics, could require flexibility in the quality measure set. This flexibility would be a key lever to adapt the Model to the unpredictable changes led by beneficiary preference, industry trends, and unforeseen nationwide events that HHAs are particularly sensitive to. We seek comment on our proposal to waive the steps outlined in section 1890A(a)(1) and (3) through (6) of the Act as applicable and to the extent necessary to test the proposed expanded Model.

7. Proposed Performance Scoring Methodology

a. Considerations for Developing the Proposed Total Performance Score Methodology

We considered several factors when we initially developed and subsequently refined the performance scoring methodology over the course of the original Model, and we are proposing to apply a similar methodology for the expanded HHVBP Model. We explain later in this section how we propose to calculate a ''performance score'' for each applicable measure for each competing HHA, which is defined as the achievement or improvement score (whichever is greater). The ''Total Performance Score,'' or ''TPS,'' is the numeric score, ranging from 0 to 100, awarded to each qualifying HHA based on the weighted sum of the performance scores for each applicable quality measure under the HHVBP Model expansion. The following principles guided the original Model's design, as well as these proposals for the expanded Model.

First, we believe the performance scoring methodology should be straightforward and transparent to HHAs, beneficiaries, and other stakeholders. HHAs should be able to clearly understand performance scoring methods and performance expectations to optimize quality improvement efforts. The public should also understand performance score methods to utilize publicly-reported information when choosing HHAs.

Second, we believe the performance scoring methodology for the proposed HHVBP Model expansion should be aligned appropriately with the quality measurements adopted for other Medicare value-based purchasing programs, including those introduced in the hospital and skilled nursing home settings. This alignment would facilitate the public's understanding of quality measurement information disseminated in these programs and foster more informed consumer decision-making about their health care choices.

Third, we believe that differences in performance scores must reflect true differences in performance. To make sure that this point is addressed in the performance scoring methodology for the proposed HHVBP Model expansion, we assessed quantitative characteristics of the measures, including the current state of measure development, number of measures, and the number and grouping of measure categories.

Fourth, we believe that both quality achievement and improvement must be measured appropriately in the performance scoring methodology for the expanded HHVBP Model. The proposed methodology specifies that performance scores under the expanded HHVBP Model would be calculated utilizing the higher of achievement or improvement scores for each measure, with achievement out of 10 points and improvement out of 9. We considered the impact of performance scores utilizing achievement and improvement on HHAs' behavior and the resulting payment implications. As under the original Model, using the higher of achievement or improvement scores would allow the Model expansion to recognize HHAs that have made improvements, though their measured performance score may still be relatively lower in comparison to other HHAs. By limiting the improvement score to a scale across 0 to 9, we prioritize achievement relative to improvement.

Fifth, we intend that the expanded Model would utilize the most currently available data to assess HHA performance, to the extent appropriate and feasible within the current technology landscape. We recognize that not all HHAs have the ability to submit data electronically or digitally

and that the proposed quality measure data would not be available instantaneously due to the time required to collect, submit, and process quality measurement information accurately; however, we intend to process data as efficiently as possible.

b. Proposed Performance Score Methodology

(1) Overview

The goal of the performance scoring methodology would be to produce a TPS for each qualifying HHA based on its raw scores on each applicable quality measure included in the expanded HHVBP Model. We would then use the HHA's TPS to determine the HHA's payment adjustment percentage. At a high level, the following summarizes the proposed steps for determining an HHA's TPS under the expanded Model, which is similar to the approach used under the original Model: (1) Each HHA would receive a raw quality measure score for each applicable measure during the performance year; (2) the HHA would receive an ''achievement score'' for each applicable measure, which is defined as a numeric value between 0 and 10 that quantifies an HHA's performance on a given quality measure compared to other HHAs in the same cohort in the baseline year (calculated using the achievement threshold and benchmark, as defined in section III.A.7.b.2. of this proposed rule); (3) each HHA would also receive an ''improvement score'' for each applicable measure, which is defined as a numeric value between 0 and 9, that quantifies an HHA's performance on a given quality measure compared to its own individual performance in the baseline year (the improvement threshold, as defined in section III.A.7.b.2. of this proposed rule); (4) each HHA would be assigned a ''performance score'' on each applicable measure that is the higher of the achievement score or the improvement score, as described in section III.A.7.b.2 of this proposed rule; and (5) each performance score would then be weighted, using each measure's assigned weight, and summed to generate the HHA's TPS, as described in section III.A.7.e. of this proposed rule. The result of this process would be a TPS for each competing HHA that can be translated into a payment adjustment percentage using the LEF applicable to each cohort, as described in section III.A.8. of this proposed rule.

Our proposal for the performance scoring methodology under the expanded HHVBP Model follows closely to that of the original Model. As discussed in more depth in the sections that follow, under the expanded HHVBP Model, we propose that we would assess each HHA's TPS based upon all applicable quality measures (defined below) in the expanded Model measure set in the applicable performance year. Each competing HHA would receive an interim assessment on a quarterly basis, as described in detail in section III.A.9.a. of this proposed rule. The performance scoring methodology would be used to determine an annual distribution of value-based payment adjustments among HHAs in a cohort so that HHAs achieving the highest performance scores would receive the largest upward payment adjustment. The proposed methodology includes three primary features, each of which is discussed in more detail in the sections that follow:

- The HHA's TPS would reflect all of the claims- and OASIS-based measures for which the HHA meets the minimum of 20 home health episodes of care per year and all of the individual components that compose an HHCAHPS survey measure for which the HHA meets the minimum of 40 HHCAHPS surveys received in the performance year, defined as ''applicable measures''.
- An HHA's TPS would be determined by weighting and summing the higher of that HHA's achievement or improvement score for each applicable measure as described in section III.A.7.b. of this proposed rule.
- The claims-based, OASIS assessment-based, and the HHCAHPS survey-based measure categories would be weighted 35 percent, 35 percent, and 30 percent, respectively, and would account for 100 percent of the TPS. If an HHA is missing a measure category or a measure within the OASIS-based measure category, the measures would be reweighted, as described further in section III.A.7.e. of this proposed rule.

As noted, we are proposing that many of the key elements from the original Model's performance scoring methodology would also apply for the expanded HHVBP Model, as we discuss in more detail in the sections that follow. The primary changes between the original Model and the expanded Model would be that first, because we are not proposing to require submission of the New Measures data, we would not consider New Measures in calculating the TPS under the expanded Model. The New Measures reporting currently accounts for 10 percent of the TPS under the original HHVBP Model. In addition, we are proposing small changes to the achievement and improvement score formulas to simplify their calculation and interpretation, without materially changing the output. We are also proposing to calculate benchmarks and achievement thresholds based on national volume-based cohorts, as opposed to the State-based cohorts under the original Model, to align with the proposal for volume-based cohorts as described in section III.A.4. of this proposed rule. Finally, we are proposing to change the potential score range for the TNC Mobility and TNC Self-Care measures from 0 to 15 points for achievement and 0 to 13.5 points for improvement as under the original Model, to 0 to 10 points for achievement and 0 to 9 points for improvement in the expanded Model. This change simplifies and aligns the calculation of the composite measure scores. The proposed weighting in the expanded Model, which follows the original Model, accounts for the intended increase in relative contribution from these composite measures to the TPS.

(2) Proposed Calculation of the Benchmark and Achievement Threshold

For scoring HHAs' performance on measures in the claims-based, OASIS-based, and the HHCAHPS survey-based categories, we propose similar elements of the scoring methodology as set forth in the original Model (as described in § 484.320), including allocating points based on achievement or improvement and calculating those points based on benchmarks and thresholds. As proposed in section III.A.5.b.1. of this proposed rule, with the exception of new HHAs, the baseline year would be CY 2019 (January 1, 2019 through December 31, 2019) for the CY 2022 performance period/CY 2024 payment year and subsequent years. All benchmarks and achievement thresholds would be set based on HHA performance in the designated baseline year.

We propose that to determine achievement points for each measure, HHAs would receive points along an achievement range, which is a scale between the achievement threshold and a benchmark. We propose to define the ''achievement threshold'' as the median (50th percentile) of all HHAs' performance scores on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts. We propose to calculate the benchmark as the mean of the top decile of all HHAs' performance scores on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts. Unlike the original Model, for the expanded HHVBP Model, we are proposing to use

a national sample separated into larger-volume and smaller-volume HHA cohorts to calculate both the achievement threshold and the benchmark, rather than calculating individual values for each selected State as in the original Model, as described in section III.A.4.b. of this proposed rule. We also propose that to determine improvement points for each measure, HHAs would receive points along an improvement range, which is a scale between an HHA's performance during the baseline year and the benchmark. The HHA's baseline year score is termed the ''improvement threshold.'' The benchmark is the same benchmark used in the achievement calculation. The achievement threshold and benchmarks for each cohort, and the improvement threshold for each HHA, calculated using baseline year performance scores, would be provided to the HHAs as soon as feasible. In addition, benchmarks, achievement thresholds, and improvement thresholds for each measure would be restated on each HHA's interim performance report (IPR). We also propose to codify the proposed definitions of achievement threshold, benchmark, and improvement threshold at § 484.345. We seek public comment on these proposals.

(i) Proposed Calculation of Achievement Score

In the original Model, we calculated the achievement score by dividing the difference between the HHA's performance score and the achievement threshold by the difference between the benchmark and the achievement threshold, multiplying the quotient by 9, and then taking the product and adding 0.5 (80 FR 68681).

Under the expanded HHVBP Model, we propose a similar approach, but with minor modifications intended to improve and simplify the calculation and the interpretation of the achievement score. Under the expanded Model, as under the original Model, we propose that an HHA could earn between 0 to 10 achievement points for each applicable measure based on its performance during the performance year relative to other HHAs in its cohort in the baseline years, quantified by the achievement threshold and the benchmark, as proposed in section III.A.7.b.2. of this proposed rule. We propose to calculate the achievement score using the following formula:

$$\text{Achievement Score} = 10 \times \left(\frac{\textit{HHA Performance Score} - \textit{Achievement Threshold}}{\textit{Benchmark} - \textit{Achievement Threshold}} \right)$$

Relative to the original Model, this proposed equation is simplified, for ease of calculation and interpretation, by multiplying it by 10, as opposed to 9, and by no longer adding 0.5. The performance rankings would not be materially affected by this change. Should the calculated achievement points exceed 10 in the equation, we propose that the maximum achievement points would be capped at 10 achievement points. As under the original Model, we propose to round each measure's achievement points up or down to the third decimal point under the expanded HHVBP Model. For example, an achievement score of 4.5555 would be rounded to 4.556. This ensures precision in scoring and ranking HHAs within each cohort. In determining an achievement score based on the HHA's raw quality measure score, we propose to apply the following rules to the achievement score calculation to ensure the achievement score falls within the range of 0 to 10 points to align with the simplified equation:

- An HHA with a raw quality measure score greater than or equal to the benchmark receives the maximum of 10 points for achievement.
- An HHA with a raw quality measure score greater than the achievement threshold (but below the benchmark) receives greater than 0 but less than 10 points for achievement (prior to rounding), by applying the achievement score formula.
- An HHA with a raw quality measure score that is less than or equal to the achievement threshold receives 0 points for achievement.

We are proposing to no longer calculate the achievement scoring for the TNC Self-Care and TNC Mobility measures out of 15 possible points, as under the original Model, and to instead simplify and align the calculation with other measures by calculating achievement scoring for the composite measures out of 10 possible points. The proposed weighting, consistent with the original Model, would already assign a larger contribution from these composite measures to the overall OASIS category score, as described in section III.A.7.e.(2).(iii). of this proposed rule. We also propose to codify these proposals at § 484.360. We seek public comment on these proposals.

(ii) Proposed Calculation of the Improvement Score

In the original Model, beginning with performance year 4, we calculated improvement scores by dividing the difference between the HHA's performance year score and the HHA's baseline year score by the difference between the benchmark and the HHA's baseline year score, multiplying the quotient by 9, and then taking the product and subtracting 0.5 to calculate the improvement score (83 FR 56543).

Similarly, under the expanded HHVBP Model, we propose to allocate 0 to 9 improvement points to an HHA for each applicable measure based upon how much an HHA's performance score in the performance year improved relative to its performance score during the baseline year. The expanded HHVBP Model aims to ensure that all HHAs provide high quality care and awarding more points for achievement than for improvement supports this goal. This continues to also align with the HVBP Program, where hospitals can earn a maximum of 9 improvement points if their measure score falls between the improvement threshold and the benchmark (76 FR 26515).

We propose to establish a unique improvement range for each measure and for each HHA that defines the difference between the HHA's baseline year score (referred to as the ''improvement threshold'') and the benchmark for the applicable measure, calculated for the applicable volume-based HHA cohort, which is the same benchmark used in the achievement scoring calculation. The following proposed improvement score formula quantifies the HHA's performance on each applicable measure in the performance year relative to its own performance in the baseline year by calculating the improvement score:

$$\text{Improvement Score} = 9 \times \left(\frac{\textit{HHA Performance Score} - \textit{HHA Improvement Threshold}}{\textit{Benchmark} - \textit{HHA Improvement Threshold}} \right)$$

Relative to the original Model, this proposed equation is simplified, for ease of calculation and interpretation, by no longer subtracting 0.5. Should the calculated points exceed 9, we propose that the maximum improvement points would be capped at 9 improvement points. Like the achievement points, we propose to round each measure's improvement points up or down to the third decimal point under the expanded HHVBP Model.

In calculating the improvement score based on the HHA's raw quality measure score, we are proposing to apply the following rules to the improvement score calculation to ensure the improvement score falls within the range of 0 to 9 points to align with the simplified equation:

- If the HHA's raw quality measure score is greater than or equal to the benchmark, the HHA would receive an improvement score of 9 points—an HHA with a raw quality measure score greater than or equal to the benchmark could still receive the maximum of 10 points for achievement.
- If the HHA's raw quality measure score is greater than its improvement threshold but below the benchmark (within the improvement range), the HHA would receive an improvement score that is greater than 0 and less than 9 (before rounding) based on the improvement score formula and as illustrated in the examples in the next section.
- If the HHA's raw quality measure score is less than or equal to or its improvement threshold for the measure, the HHA would receive 0 points for improvement.

We are proposing to no longer calculate the improvement scoring for the TNC Self-Care and TNC Mobility measures out of 13.5 possible points, as under the original Model, and to instead simplify and align the calculation with other measures by calculating improvement scoring for the composite measures out of 10 possible points. The proposed weighting, consistent with the original Model, would already assign a larger contribution from these composite measures to the overall OASIS category, as described in section III.A.7.e.(2).(iii). of this proposed rule. We also propose to codify these proposals at § 484.360. We seek public comment on these proposals.

(iii) Examples of Calculating Achievement and Improvement Scores

For illustrative purposes, the following examples demonstrate how the performance scoring methodology would be applied in the context of the measures in the claims-based, OASIS-based, and the HHCAHPS survey-based categories. These HHA examples are based on illustrative data from CY 2019 (for the baseline year) and hypothetical data for CY 2022 (for the performance year). The benchmark calculated for the Dyspnea measure is 97.676 for HHA A (calculated as the mean of the top decile of HHA performance from the CY 2019 baseline year for the volume-based cohort). The achievement threshold is 75.358 (calculated as the median or the 50th percentile of HHA performance from the CY 2019 baseline year for the same volume-based cohort).

Figure 4 shows the scoring for HHA 'A' as an example. HHA A's CY 2022 performance year score for the Dyspnea measure was 98.348, exceeding both the CY 2019 achievement threshold and benchmark, which means that HHA A earned the maximum 10 points based on its achievement score. Its improvement score is irrelevant in the calculation because the HHA's performance score for this measure exceeded the benchmark, and the maximum number of improvement points possible is 9.

Figure 4 also shows the scoring for HHA 'B.' HHA B's performance on the Dyspnea measure was 52.168 for the CY 2019 baseline year (HHA B's improvement threshold) and increased to 76.765 (which is above the achievement threshold of 75.358) for the CY 2022 performance year. To calculate the achievement score, HHA B would earn 0.630 achievement points, calculated as follows: $10 * (76.765 - 75.358)/(97.676 - 75.358) = 0.630$.[25] Calculating HHA B's improvement score yields the following result: Based on HHA B's period-to-period improvement, from 52.168 in the baseline year to 76.765 in the performance year, HHA B would earn 4.864 improvement points, calculated as follows: $9 * (76.765 - 52.168)/(97.676 - 52.168) = 4.864$.[26] Because the higher of the achievement and improvement scores is used, HHA B would receive 4.864 improvement points for this measure.

In Figure 5, HHA 'C' yielded a decline in performance on the TNC Self-Care measure, falling from 70.266 to 58.487. HHA C's performance during the performance year was lower than the achievement threshold of 75.358 and, as a result, HHA C would receive zero points based on achievement. It would also receive zero points for improvement because its performance during the performance year was lower than its improvement threshold.

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[25] The proposed formula for calculating achievement points is 10 * (HHA Performance Year Score – Achievement Threshold)/(Benchmark – Achievement Threshold).

[26] The proposed formula for calculating improvement points is 9 * (HHA Performance Year Score – HHA Improvement Threshold)/(HHA Benchmark – HHA Improvement Threshold).

FIGURE 4: EXAMPLE OF AN HHA EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING

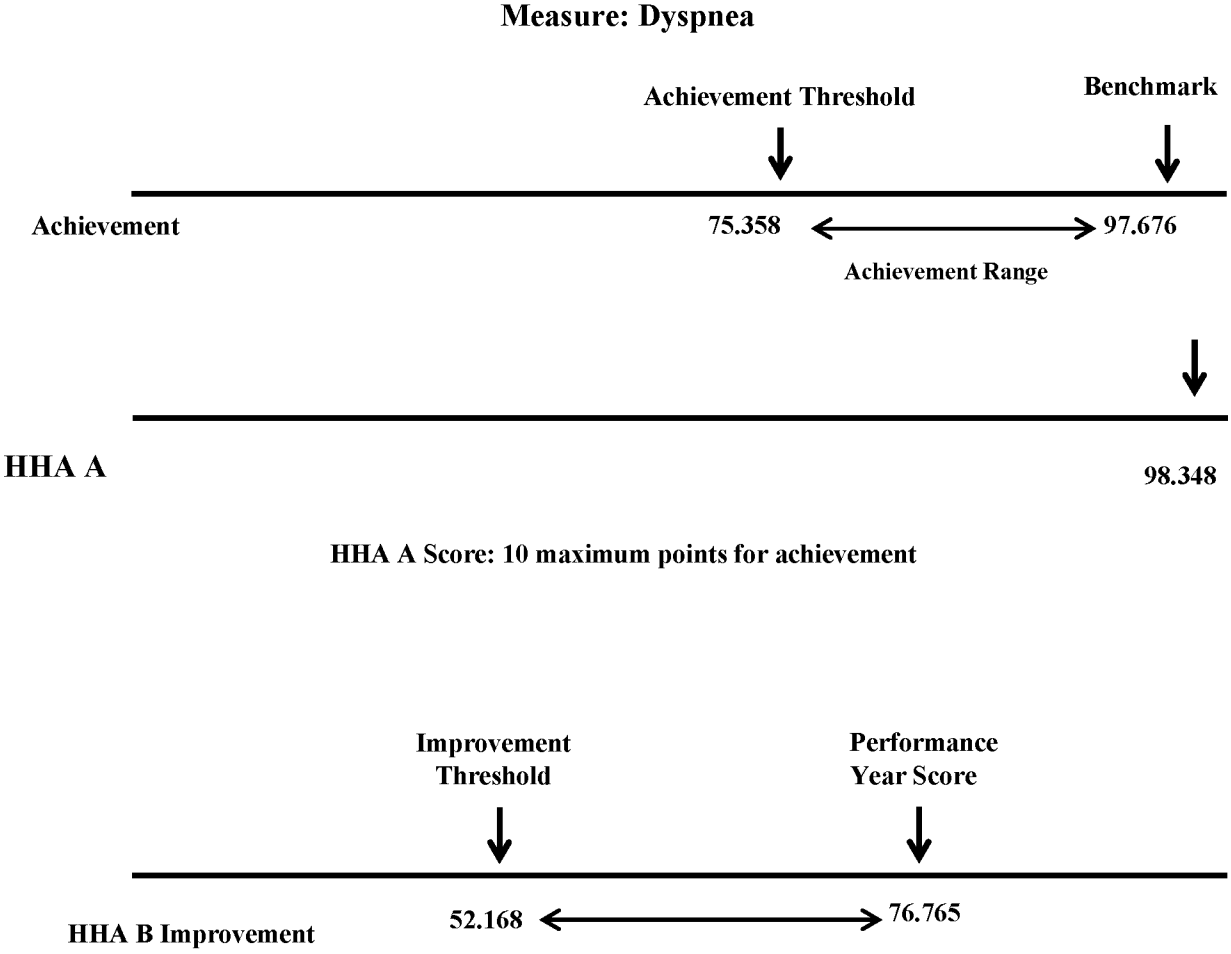
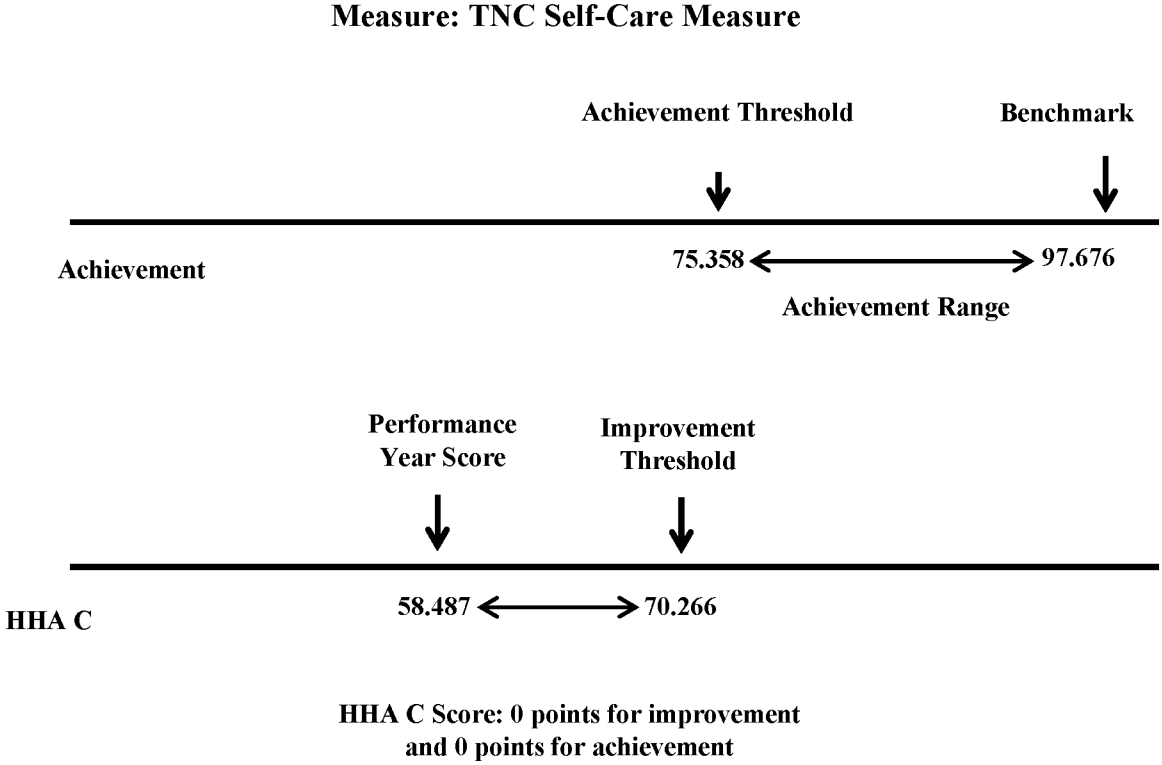


FIGURE 5: EXAMPLE OF AN HHA NOT EARNING POINTS BY ACHIEVEMENT OR IMPROVEMENT SCORING



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c. Minimum Threshold Number of Cases for Claims-Based, OASIS-Based, and HHCAHPS Survey-Based Measures To Receive a Measure Score

For the expanded Model, we are proposing to apply the same policies around minimum case counts for each measure as implemented under the original Model, as described in proposed § 484.345. We propose to continue to award an HHA the higher-of achievement or improvement points, as proposed previously, for ''applicable measures'' only. Under this proposal, for the measures included in the claims-based and OASIS-based measure categories, an ''applicable measure'' is one for which the HHA has provided a minimum of 20 home health episodes of care per year and, therefore, has at least 20 cases in the denominator. We are proposing this minimum to align with the original HHVBP Model and the measure specifications used for the Patient Quality of Care Star Ratings.[27] For the individual components that compose the HHCAHPS survey measure, an ''applicable measure'' means a component for which a competing HHA has submitted a minimum of 40 completed HHCAHPS surveys. A minimum of 40 completed HHCAHPS surveys for each applicable measure for the expanded Model represents a balance between providing meaningful data for payment adjustments and having more HHAs with sufficient numbers of measures with performance scores. Moreover, using a minimum of 40 completed HHCAHPS surveys for each applicable measure would align with the Patient Survey Star Ratings on Home Health Compare.[28]

We also propose to codify this proposed definition of an ''applicable measure'' at § 484.345. We seek public comment on these proposals.

d. Minimum Number of Applicable Measures for an HHA To Receive a Total Performance Score

For the expanded Model, we are proposing to apply the same policies around the minimum number of applicable measures to receive a TPS, as implemented under the original Model. We are proposing that, beginning with the CY 2022 performance year and for subsequent years, an HHA that does not meet the minimum threshold of cases or completed HHCAHPS surveys, as applicable, on five or more measures under the expanded Model would not receive a TPS or a payment adjustment based on that performance year. Under the expanded Model, this means 5 of the 12 possible applicable measures in the measure set, which includes two claims-based measures, 5 OASIS-based measures, and the 5 components from the HHCAHPS survey measure. HHAs without five applicable measures for a performance year would be paid for HHA services in an amount equivalent to the amount that would have been paid under section 1895 of the Act. We believe that a minimum of five applicable measures allows for a robust basis on which to adjust payment while also maximizing the number of HHAs eligible for the payment adjustment.

Although those HHAs that do not meet this minimum would not be subject to payment adjustments under the expanded Model, we propose that other applicable policies under the expanded HHVBP Model would still apply. We propose that these HHAs

[27] Centers for Medicare & Medicaid Services. (2020, April). Quality of Patient Care Star Ratings Methodology. Home Health Quality of Patient Care Star Ratings. *https://www.cms.gov/files/document/quality-patient-care-star-ratings-methodologyapril-2020.pdf.*

[28] Centers for Medicare & Medicaid Services. (2016, March). Technical Notes for HHCAHPS Star Ratings. Home Health HHCAHPS Star Ratings. *https://homehealthcahps.org/Portals/0/HHCAHPS_Stars_Tech_Notes.pdf.*

would receive IPRs for any measures that meet the definition of applicable measure, and they would continue to have future opportunities to compete for payment adjustments. Based on the most recent data available, the vast majority of HHAs are reporting on at least five applicable measures. In 2019, those with less than five applicable measures account for less than 2.4 percent of the claims made (and 2.0 percent of claims payments made) across the 9,526 HHAs delivering care nationwide.

We also propose to codify this proposal at § 484.360(c). We seek public comment on this proposal.

e. Proposed Weights for the Claims-Based, OASIS-Based, and HHCAHPS Survey Measures

Except for removing the New Measures category, for the expanded HHVBP Model, we are generally proposing the same policies regarding the weighting of measures and the re-distribution of weights when measures or measure categories are missing as under the original Model (83 FR 56536).

(1) Proposed Weighting and Re-Distribution of Weights Between the Measure Categories

In this proposed rule, we propose to group the expanded Model proposed measures into measure categories based on their data source as indicated in Table 28: Claims-based, OASIS-based, and the HHCAHPS survey-based. We propose that claims-based, OASIS-based, and the HHCAHPS survey-based categories would be weighted 35 percent, 35 percent, and 30 percent, respectively, when the HHA has applicable measures in all three categories and otherwise meets the minimum threshold to receive a TPS. Together, all three categories would account for 100 percent of the TPS. The measure weights reflect prioritization of the two claims-based measures because they may have a greater impact on reducing Medicare expenditures. In addition, we also place slightly more weight on the OASIS-based measures since they represent a larger variety of measures covering a range of quality topics as compared to the HHCAHPS survey measure.

We also propose that where an HHA is missing all measures from a single measure category, the weights for the remaining two measure categories would be redistributed such that the proportional contribution remains consistent with the original weights. For instance, some smaller-volume HHAs may be missing the HHCAHPS survey measure, which would require re-distributing weights to the claims-based (otherwise weighted 35 percent) and OASIS-based (otherwise weighted 35 percent) measure categories, such that the claims-based and OASIS-based measure categories would each be weighted at 50 percent of the total TPS. Where an HHA is missing the claims-based category, the OASIS-based (otherwise weighted 35 percent) and the HHCAHPS survey (otherwise weighted 30 percent) measure categories would be reweighted to 53.85 percent for the OASIS-based measures and 46.15 percent for the HHCAHPS survey measure.[29] [30] Finally, we propose that if two measure categories are missing, the remaining category would be weighted 100 percent. We refer readers to Table 29 for the distribution of measure category weights under various scenarios.

(2) Proposed Quality Measure Weights Within Measure Categories

Within the measure categories, we are proposing to weight certain individual measures differently than other measures in the same category.

(i) HHCAHPS Survey Measure Category

For the HHCAHPS survey measure category, we propose that all five components are weighted equally to determine the overall HHCAHPS survey measure percentage, which would contribute 30 percent to the overall TPS. This measure category would not require re-distribution of weights for the individual components because HHAs either meet the minimum requirement for number of completed surveys for all HHCAHPS survey measure components or they do not meet the minimum requirements.

(ii) Claims-Based Measure Category

For the claims-based measure category, we are proposing to weight the ACH measure at 75 percent, and the ED Use measure at 25 percent of the total measure weight for this measure category. We are proposing to place a higher weight on the ACH measure because it reflects a more severe health event and because inpatient hospitalizations generally result in more Medicare spending than the average emergency department visit that does not lead to an acute hospital admission. Like the HHCAHPS survey measure components, an HHA would either have sufficient volume for both claims-based measures to be applicable measures or it would have data for neither measure since both measures require the same minimum of 20 episodes per performance year. Consequently, re-distributing weights for either measure within the claims-based measure category should not be necessary.

(iii) OASIS-Based Measure Category

For the OASIS-based measure category, we propose to weight both the TNC Self Care and TNC Mobility measures at 25 percent each; and the Dyspnea, Discharged to Community, and Oral Medications measures at 16.67 percent each of the total measure weight for this measure category. Both the TNC Self-Care and TNC Mobility measures are composed of several measures that are consolidated into two composite measures; because of this, we are proposing to weight them slightly more than the other three measures, which are not composite measures, as under the original Model. Under this proposal, should any measures in the category be missing, we propose to re-distribute weights across the measures such that the original proportions are maintained. For instance, should an HHA be missing both the TNC Self-Care and Dyspnea measures, the remaining measures would be weighted as 42.85 percent for the TNC Mobility measure, 28.57 percent for the Discharged to Community measure, and 28.57 percent for the Oral Medications measure, which reflects the relative ratios of 25 percent to 16.67 percent to 16.67 percent, respectively.[31] [32] [33]

See Table 28 for a comprehensive list of the proposed within-category measure weights.

[29] OASIS-based measures reweighting = 35% original OASIS weight/(35% original OASIS weight + 30% original HHCAHPS weight) = 53.85% revised OASIS weight.

[30] HHCAHPS reweighting = 30% original HHCAHPS weight/(35% original OASIS weight + 30% original HHCAHPS weight) = 46.15% revised HHCAHPS weight.

[31] TNC Mobility reweighting = 25% original TNC Mobility weight/(25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 42.85% revised TNC Mobility weight.

[32] Discharged to Community reweighting = 16.67% original Discharged to Community weight/(25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 28.57% revised Discharged to Community weight.

[33] Oral Medications reweighting = 16.67% original Oral Medications weight/(25% original TNC Mobility weight + 16.67% original Discharged to Community weight + 16.67% original Oral Medications weight) = 28.57% revised Oral Medications weight.

TABLE 28: PROPOSED WITHIN-CATEGORY MEASURE WEIGHTS

Measure Category	Quality Measures	Within-category Weight (percentage)
OASIS	TNC Self-Care	25.00
	TNC Mobility	25.00
	Dyspnea	16.67
	Discharged to Community	16.67
	Oral Medications	16.67
Claims	ACH	75.00
	ED Use	25.00
HHCAHPS Survey	HHCAHPS Professional Care	20.00
	HHCAHPS Communication	20.00
	HHCAHPS Team Discussion	20.00
	HHCAHPS Overall Rating	20.00
	HHCAHPS Willingness to Recommend	20.00

Table 29 presents the proposed weights for the proposed measures and measure categories under various reporting scenarios.

TABLE 29: PROPOSED QUALITY MEASURE WEIGHTING AND RE-WEIGHTING SCHEDULE

	Measure Reporting Scenarios			
Measure	All Measures	No HHCAHPS	No Claims	No Claims or HHCAHPS
OASIS				
TNC Self-Care	8.75%	12.50%	13.46%	25.00%
TNC Mobility	8.75%	12.50%	13.46%	25.00%
Oral Medications	5.83%	8.33%	8.98%	16.67%
Dyspnea	5.83%	8.33%	8.98%	16.67%
Discharged to Community	5.83%	8.33%	8.98%	16.67%
Total for OASIS-based measures	*35.00%*	*50.00%*	*53.85%*	*100.00%*
Claims				
ACH	26.25%	37.50%	0.00%	0.00%
ED Use	8.75%	12.50%	0.00%	0.00%
Total for claims-based measures	*35.00%*	*50.00%*	*0.00%*	*0.00%*
HHCAHPS Survey Measure Components				
HHCAHPS Professional Care	6.00%	0.00%	9.23%	0.00%
HHCAHPS Communication	6.00%	0.00%	9.23%	0.00%
HHCAHPS Team Discussion	6.00%	0.00%	9.23%	0.00%
HHCAHPS Overall Rating	6.00%	0.00%	9.23%	0.00%
HHCAHPS Willingness to Recommend	6.00%	0.00%	9.23%	0.00%
Total for the HHCAHPS Survey-based measure	*30.00%*	*0.00%*	*46.15%*	*0.00%*

We also propose to codify these proposals at § 484.360. We seek public comment on these proposals.

f. Examples of the Total Performance Score Calculation

The following are two examples of the proposed performance score calculation, beginning with the assigned achievement vs. improvement points. The following describes the TPS calculations for HHA ''D'' and HHA ''E.''

In this first example, out of a possible 12 applicable measures, which includes two claims-based measures, five OASIS assessment-based measures, and five components that make up the HHCAHPS survey measure, HHA ''D'' has at least 20 episodes of care and received at least 40 completed HHCAHPS surveys in the 12-month performance year, which means the HHA received scores on all 12 quality

measures. Under the proposed scoring methodology outlined previously, for HHA D, the measure category weights would be as follows: 35 percent for the claims-based measures, 35 percent for the OASIS assessment-based measures, and 30 percent for the HHCAHPS Survey-based measures. See Table 30 for a detailed calculation of the TPS. For each measure in column 1, HHA D receives the highest of its achievement or improvement score, which is listed in column 2. Each applicable measure's weight is listed in column 3. To determine the weighted points in column 4, multiply the measure score in column 2 by the measure's weight in column 3 and then by 10. The total performance score is the sum of all the weighted points listed in column 4. In the case of HHA D, the TPS is 46.021.

TABLE 30: HHA D TOTAL PERFORMANCE SCORE EXAMPLE

① Quality Measure	② Points for Applicable Measures	③ Proposed Weight (percentage)	④ Weighted Points
OASIS			
TNC Self-care	7.661	8.75	6.703
TNC Mobility	5.299	8.75	4.637
Oral Medications	3.302	5.83	1.925
Dyspnea	4.633	5.83	2.701
Discharged to Community	0.618	5.83	0.360
Claims			
ACH	1.180	26.25	3.098
ED Use	0.000	8.75	0.000
HHCAHPS Survey Components			
HHCAHPS Professional Care	10.000	6.00	6.000
HHCAHPS Communication	10.000	6.00	6.000
HHCAHPS Team Discussion	10.000	6.00	6.000
HHCAHPS Overall Rating	5.921	6.00	3.553
HHCAHPS Willingness to Recommend	8.406	6.00	5.044
Total Performance Score		**100.00**	**46.021**

In the second example, HHA ''E'' has only seven applicable measures. Because it did not receive the minimum count of HHCAHPS surveys for all components, HHA E did not receive any scores on the HHCAHPS Survey components. Where an HHA is missing the HHCAHPS Survey components, the HHA's HHCAHPS Survey measure category is re-weighted at 0% and the remaining two measure categories are re-weighted such that their proportional contribution remains consistent with the original weights and the total of the weights sums to 100 percent. Based on the ratio of the original weights for the claims-based (35 percent) and the OASIS-based (35 percent) measure categories, each category contributes 50 percent to the TPS. See Table 30 for the detailed calculation of the TPS. For each applicable measure in column 1, HHA E received the highest of its achievement or improvement score, which is listed in column 2. Column 2 lists N/A for each of the HHCAHPS Survey measure components since this HHA had fewer than 40 HHCAHPS surveys in the performance year. Each applicable measure's weight is listed in column 3. To determine the weighted points in column 4, multiply the measure score in column 2 by the applicable measure's weight in column 3 and then by 10. The total performance score is the sum of all the weighted points listed in column 4. In the case of HHA E, the TPS is 27.750.

TABLE 31: HHA E TOTAL PERFORMANCE SCORE EXAMPLE

① Quality Measures	② Points for Applicable Measures	③ Proposed Re-Weighting (percentage)	④ Re-Weighted Points
OASIS			
TNC Self-care	7.661	12.5	9.576
TNC Mobility	5.299	12.5	6.624
Oral Medications	3.302	8.33	2.751
Dyspnea	4.633	8.33	3.859
Discharged to Community	0.618	8.33	0.515
Claims			
ACH	1.180	37.50	4.425
ED Use	0.000	12.50	0.000
HHCAHPS Survey Components			
HHCAHPS Professional Care	N/A	0.00	N/A
HHCAHPS Communication	N/A	0.00	N/A
HHCAHPS Team Discussion	N/A	0.00	N/A
HHCAHPS Overall Rating	N/A	0.00	N/A
HHCAHPS Willingness to Recommend	N/A	0.00	N/A
Total Performance Score		**100.00**	**27.750**

8. Proposed Payment Adjustment Methodology

We finalized the use of the Linear Exchange Function (LEF) for the original Model (80 FR 68686) because it was the simplest and most straightforward option to provide the same marginal incentives to all HHAs, and we believe the same to be true for the HHVBP Model expansion. The LEF is used to translate an HHA's TPS into a percentage of the value-based payment adjustment earned by each HHA. Performance measurement is based on a linear exchange function which only includes competing-HHAs.

Under the expanded HHVBP Model, we propose to codify at § 484.370 a methodology for applying value-based payment adjustments to home health services. We propose that payment adjustments would be made to the HH PPS final claim payment amount as calculated in accordance with HH PPS regulations at § 484.205 using a LEF, similar to the methodology utilized by the HVBP Program (76 FR 26533). We propose the function's intercept at zero percent, meaning those HHAs that have a TPS that is average in relationship to other HHAs in their cohort would not receive any payment adjustment. Under this proposal, payment adjustments for each HHA with a score above zero percent would be determined by the slope of the LEF. We propose to set the slope of the LEF for the given performance year so that the estimated aggregate value-based payment adjustments for that performance year are equal to 5% (the proposed maximum payment adjustment for CY 2024) of the estimated aggregate base operating payment amount for the corresponding payment year, calculated separately for the larger and smaller volume cohorts nationwide. The estimated aggregate base operating payment amount is the total amount of payments made to all the HHAs by Medicare nationwide in each of the larger- and smaller-volume cohorts.

We propose that the LEF would be calculated using the following steps, after calculating and ranking the Total Performance Score (TPS) (the range of the TPS is 0–100) for each HHA in the cohort:

- Step 1, Determine the 'Prior Year Aggregate HHA Payment Amount' that each HHA was paid in the prior year.
- Step 2, Determine the 'X-percent (the applicable payment year payment adjustment percent) Payment Reduction Amount' by multiplying the Prior Year Aggregate HHA Payment Amount per HHA by the 'X-percent Reduction Rate'; the sum of these amounts is the numerator of the LEF.
- Step 3, Determine the 'TPS Adjusted Reduction Amount' by multiplying the 'X-percent Payment Reduction Amount' by the TPS/100 . The sum of these amounts is the denominator of the LEF.
- Step 4, Calculate the LEF by dividing the sum of all HHAs' 'X-percent Payment Reduction Amount' by the sum of the 'TPS Adjusted Reduction Amount'.
- Step 5, Determine the 'Final TPS Adjusted Payment Amount' by multiplying the LEF by the 'TPS Adjusted Reduction Amount' for each HHA.
- Step 6, Determine the 'Quality Adjusted Payment Rate' by dividing the 'Final TPS Adjusted Payment Amount' by the 'Prior Year Aggregate HHA Payment Amount'.
- Step 7, Determine the 'Final Percent Payment Adjustment' that will be applied to the HHA payments by subtracting the 'X-percent Reduction Rate' from the 'Quality Adjusted Payment Rate'.

Table 32 provides an example of how the LEF would be calculated and how it would be applied to calculate the percentage payment adjustment to an HHA's TPS. For this example, we applied the maximum 5-percent payment adjustment proposed for the expanded HHVBP Model for the CY 2024 payment year.

Step #1 involves the calculation of the 'Prior Year Aggregate HHA Payment Amount' (C2 in Table 32) that each HHA was paid from claims data under the HH PPS in the year prior to the performance year. For the CY 2024 payment year, from claims data, all payments are summed together for each HHA for CY 2021, the year prior to the performance year.

Step #2 involves the calculation of the '5-percent Payment Reduction Amount' (C3 of Table 32 for each HHA, which is calculated by multiplying the 'Prior Year Aggregate HHA Payment Amount', from Step #1 by the '5-percent Payment Reduction Rate'. The aggregate of the '5-percent Payment Reduction Amount' is the numerator of the LEF.

Step #3 involves the calculation of the 'TPS Adjusted Reduction Amount' (C4 of Table 32) by multiplying the '5-percent Payment Reduction Amount' from Step #2 by the TPS (C1) divided by 100. The aggregate of the 'TPS Adjusted Reduction Amount' is the denominator of the LEF.

Step #4 involves calculating the LEF (C5 of Table 32) by dividing the sum of '5- percent Payment Reduction Amount' calculated in Step #2 by the sum of 'TPS Adjusted Reduction Amount' calculated in Step #3.

Step #5 involves the calculation of the 'Final TPS Adjusted Payment Amount' (C6 of Table 32) by multiplying the 'TPS Adjusted Reduction Amount' from Step #3 (C4) by the LEF from Step #4 (C5). The 'Final TPS Adjusted Payment Amount' is an intermediary value used to calculate 'Quality Adjusted Payment Rate'.

Step #6 involves the calculation of the 'Quality Adjusted Payment Rate' (C7 of Table 32) by dividing the 'Final TPS Adjusted Payment Amount' from Step #5 by the 'Prior Year Aggregate HHA Payment Amount' from Step #1. This is an intermediary step to determining the payment adjustment rate.

Step #7 involves the calculation of the 'Final Percent Payment Adjustment' (C8 of Table 32) by subtracting 5 percent from 'Quality Adjusted Payment Rate'. The 'Final Percent Payment Adjustment' would be applied to the HHA payments for the payment adjustment year. We propose that the payment adjustment percentage would be capped at no more than plus or minus 5 percent for the applicable performance year and the payment adjustment would occur on the final claim payment amount for the applicable payment year.

We also propose to codify this payment methodology policy at § 484.370. We invite comments on this proposal.

TABLE 32: 5-PERCENT REDUCTION SAMPLE

		Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
HHA	TPS	Prior Year Aggregate HHA Payment Amount*	5-Percent Payment Reduction Amount (C2*5 percent)	TPS Adjusted Reduction Amount (C1/100)*C3	Linear Exchange Function (LEF) (Sum of C3/ Sum of C4)	Final TPS Adjusted Payment Amount (C4*C5)	Quality Adjusted Payment Rate (C6/C2)	Final Percent Payment Adjustment +/- (C7-5%)
	(C1)	(C2)	(C3)	(C4)	(C5)	(C6)	(C7)	(C8)
HHA1	38	$100,000	$5,000	$1,900	1.931	$3,669	3.669%	-1.331%
HHA2	55	$145,000	$7,250	$3,988	1.931	$7,701	5.311%	0.311%
HHA3	22	$800,000	$40,000	$8,800	1.931	$16,995	2.124%	-2.876%
HHA4	85	$653,222	$32,661	$27,762	1.931	$53,614	8.208%	3.208%
HHA5	50	$190,000	$9,500	$4,750	1.931	$9,173	4.828%	-0.172%
HHA6	63	$340,000	$17,000	$10,710	1.931	$20,683	6.083%	1.083%
HHA7	74	$660,000	$33,000	$24,420	1.931	$47,160	7.146%	2.146%
HHA8	25	$564,000	$28,200	$7,050	1.931	$13,615	2.414%	-2.586%
Sum			$172,611	$89,379		$172,611		

*Example cases.

9. Performance Feedback Reports

We propose to use two types of reports that would provide information on performance and payment adjustments under the expanded HHVBP Model. These reports would mirror those we have distributed to HHAs under the original Model.

a. Proposed Interim Performance Report

The first report is the Interim Performance Report (IPR) that would be distributed to HHAs quarterly. The IPR would contain information on the interim quality measure performance based on the 12 most recent months of data available. The IPR would provide feedback to HHAs regarding performance relative to quality measure achievement thresholds and benchmarks and would provide competing HHAs the opportunity to assess and track their performance relative to their peers and their own past performance. HHAs would receive both a preliminary and final version of the IPR each quarter. The Final IPR would become available, as soon as administratively feasible, after the preliminary IPR is distributed and after recalculation requests are processed, in accordance with the process in section III.A.10. of this proposed rule (Appeal Processes).

Beginning with the data collected during the first quarter of CY 2022 (that is, data for the period January 1, 2022 to March 31, 2022), and for every quarter of the expanded HHVBP Model thereafter, we propose to provide each HHA with an IPR that contains information on its performance during the 12 most recent months of data available. We propose to provide the 12 most recent months of data because the

OASIS and claims data are available with different lag times and measures are reported in 12-month intervals on Care Compare. By using 12 months of data, we are able to remove seasonality issues and help to ensure a sufficient number of cases to provide meaningful information to HHAs. By providing HHAs with the most recent 12 months of data, the IPRs provide as close to real-time performance information as possible. We expect to make the first IPR available in July 2022 and make IPRs for subsequent quarters available in October, January, and April. The July 2022 IPR would be the first IPR issued that includes CY 2022 performance year data for the first quarter quality measure performance scores on the proposed OASIS-based measures and baseline data for the HHCAHPS survey and claims-based measures. We propose that the IPRs would include a competing HHA's expanded HHVBP Model-specific performance results with a comparison to other competing HHAs within its applicable nationwide cohort (larger- or smaller-volume). We propose that the IPRs would be made available to each HHA through a CMS data platform, such as the internet Quality Improvement and Evaluation System (iQIES), and would include each HHA's relative estimated ranking amongst its cohort along with measurement points and total performance score based on the 12 most recent months of data available. We note that the IPRs would likely differ from the final data used to assess performance during a given performance year because the time periods used to develop the IPR data (the 12 most recent months) would differ from the actual performance years under the expanded Model (for example, CY 2022 data used to determine CY 2024 payment adjustments).

These performance results would complement quality data sources provided through the iQIES and other quality tracking systems possibly being employed by HHAs to help drive quality improvement. The iQIES-generated reports would provide quality data earlier than the expanded HHVBP Model-specific performance reports (that is, IPR or Annual) because iQIES-generated reports are not limited by a quarterly run-out of data and a calculation of competing peer-rankings. The primary difference between iQIES-generated reports and expanded HHVBP Model-specific performance reports is that the Model-specific performance report we propose would consolidate the applicable performance measures used in the expanded HHVBP Model, provide a peer-ranking to other competing HHAs within the same volume-based cohort, and provide the TPS based on the interim data. In addition, Model-specific performance reports would provide the competing HHAs with a Scorecard and TNC Change Reference. The TNC Change Reference data would help HHAs gauge their performance on the individual OASIS items included in the two composite measures. It would also tell HHAs the percentage of episodes in which there was no change, positive change, or negative change for each OASIS item. The Scorecard would help HHAs better understand how each individual measure contributes to the TPS. For more information on the accessibility and functionality of the iQIES, please reference the iQIES manuals.[34] We note that all quality measures, except for the TNC Mobility and TNC Self-Care measures and the HHCAHPS survey measure, in the proposed measure set for the CY 2022 performance year of the expanded HHVBP Model are already made available in the iQIES. For the HHCAHPS survey measure, HHAs can access their Data Submission Reports on *https://homehealthcahps.org* under the ''For HHAs'' tab. We also suggest HHAs contact their survey vendor regarding data on the HHCAHPS survey measure.

We invite public comment on our proposals.

b. Proposed Annual TPS and Payment Adjustment Report

We propose that the second report, the Annual TPS and Payment Adjustment Report (Annual Report), would be made available to each of the competing HHAs in approximately August of each year preceding the payment adjustment year, expected beginning in August 2023. We propose to make the report available via a CMS data platform, such as the iQIES. The Annual Report would focus primarily on the HHA's payment adjustment percentage for the upcoming CY and include an explanation of when the adjustment would be applied and how this adjustment was determined relative to the HHA's performance scores. Each competing HHA would receive its own confidential Annual Report viewable only to that HHA. We propose that the Annual Report would have three versions: A Preview Annual Report, a Preliminary Annual Report (if applicable), and a Final Annual Report. We would make available to each competing HHA the Preview Annual Report in approximately August of each year preceding the calendar year for which the payment adjustment would be applied. We propose that HHAs would have 15 days to review and request recalculations in accordance with the proposed process discussed in section III.A.10. of this proposed rule (Appeal Processes). For HHAs that request a recalculation, we would make available a Preliminary Annual Report as soon as administratively feasible after the recalculation request is processed. If we do not receive a recalculation request as a result of the Preview Annual Report, a Preliminary Annual Report would not be issued. We propose that HHAs that receive a Preliminary Annual Report would have 15 days to review and submit a reconsideration request in accordance with the proposed process discussed in section III.A.10. of this proposed rule (Appeal Processes). As under the original Model, we propose to make available the Final Annual Report after all reconsideration requests are processed and no later than 30 calendar days before the payment adjustment takes effect annually, both for those HHAs that requested a reconsideration and all other competing HHAs.

Under this proposed approach, HHAs would be notified in advance of the first annual total performance score and payment adjustment being finalized for CY 2024. The total performance score and payment adjustment would be based on the CY 2022 performance year (January 1, 2022 to December 31, 2022), with the first payment adjustment to be applied to each HH PPS final claim payment amount as calculated in accordance with HH PPS policies as codified at § 484.205 for HHA services furnished January 1, 2024 through December 31, 2024.

Subsequent payment adjustments would be calculated based on the applicable full calendar year of performance data from the final IPRs, with competing HHAs notified and payments adjusted, respectively, every year thereafter. As a sequential example, the second payment adjustment would apply for services furnished January 1, 2025 through December 31, 2025, based on a full 12 months of the CY 2023 performance year. Notification of the second pending payment adjustment would occur in approximately August 2024 when the Preview Annual Report is issued, followed by the Preliminary (if applicable) and Final Annual Reports, as described previously.

Data related to performance on quality measures would continue to be provided for the baseline year and all performance years of the expanded

[34] iQIES manuals are available at *https://qtso.cms.gov/software/iqies/reference-manuals.*

Model via a CMS data platform, such as the iQIES (this platform would present and might archive the previously described IPR and Annual Reports).

Table 33 is a sample timeline showing the availability of each expanded HHVBP Model-specific performance report and the data included for the CY 2022 performance year and CY 2024 payment year.

TABLE 33: SAMPLE TIMELINE FOR CY 2022 PERFORMANCE YEAR AND CY 2024 PAYMENT YEAR BY REPORT TYPE AND DATA TYPE

Report Type (Approximate Date Issued)	OASIS-Based Measures	Claims-Based and HHCAHPS-Based Measures
July 2022 IPR (July 2022)	12 months ending 3/31/2022	Baseline data only
October 2022 IPR (Oct 2022)	12 months ending 6/30/2022	12 months ending 3/31/2022
January 2023 IPR (Jan 2023)	12 months ending 9/30/2022	12 months ending 6/30/2022
April 2023 IPR (April 2023)	12 months ending 12/31/2022	12 months ending 9/30/2022
July 2023 IPR (July 2023)	12 months ending 3/31/2023	12 months ending 12/31/2022
Annual TPS and Payment Adjustment Report (Aug 2023)*	12 months ending 12/31/2022	12 months ending 12/31/2022

*The Annual Report made available to HHAs in approximately August 2023 is the Preview Annual Report. The Final Annual Report is issued after the recalculation and reconsideration request periods and no later than 30 days prior to the calendar year which the payment adjustment will take effect.

We seek public comment on our proposals related to the Interim Performance and Annual Reports.

10. Appeals Processes

As codified at § 484.335, the appeals process under the original HHVBP Model allows HHAs to submit recalculation requests for the IPRs and Annual TPS and Payment Adjustment Report. Under this process, an HHA may also make a reconsideration request if it disagrees with the results of a recalculation request for the Annual TPS and Payment Adjustment Report. We refer the reader to the CY 2017 HH PPS final rule for further discussion of the appeals process under the original HHVBP Model (81 FR 76747 through 76750).

Under the expanded Model, we propose to use the same appeals process as the original Model. We propose that competing HHAs be provided the opportunity to appeal certain information provided in the IPRs and the Annual Report, as discussed in more detail in the following sections.

a. Proposed Recalculation Request Process

Under the expanded HHVBP Model, we propose that HHAs be provided two separate opportunities to review scoring information and request recalculations.

HHAs would have the opportunity to request a recalculation if a discrepancy is identified due to a CMS error in calculations after review of their: (1) Preliminary IPRs following each quarterly posting; or (2) Preview Annual Report. Specifically, we propose that an HHA would have 15 calendar days from the date either the Preliminary IPR or the Preview Annual Report is provided to request a recalculation of measure scores if it believes there is evidence of a discrepancy in the calculation of the measure. We propose that we would adjust the score if it is determined that the discrepancy in the calculated measure scores was the result of our failure to follow measurement calculation protocols. An HHA would also have the opportunity to request recalculation if it wishes to dispute the application of the formula to calculate the payment adjustment percentage.

Under this proposal, for both the Preliminary IPRs and the Preview Annual Report, competing HHAs would only be permitted to request scoring recalculations or, for the Preview Annual Report, to dispute the application of the formula used to calculate the payment adjustment percentage, and must include a specific basis for the requested recalculation. Any changes to underlying measure data cannot be made. We would not provide HHAs with the underlying source data utilized to generate performance measure scores.

We propose that HHAs that choose to request a recalculation would submit recalculation requests for both quarterly Preliminary IPRs and for the Preview Annual Reports via instructions provided on a CMS web page. We propose that the request form would be entered by the primary point of contact, a person who has authority to sign on behalf of the HHA.

We propose that recalculation requests (quarterly Preliminary IPR or Preview Annual Report recalculations)

must contain all of the following information:

- The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).
- The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.
- Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).
- A copy of any supporting documentation the HHA wishes to submit in electronic form via the Model-specific web page.

Following receipt of a recalculation request, we propose that CMS or its agent would—

- Provide an email acknowledgement, using the contact information provided in the recalculation request, to the HHA contact notifying the HHA that the request has been received;
- Review the request to determine validity, and determine whether the requested recalculation results in a score change altering performance measure scores or the HHA's TPS;
- If the recalculation request results in a performance measure score change, conduct a review of data and if an error is found, recalculate the TPS using the corrected performance data; and
- Provide a formal response to the HHA contact, using the contact information provided in the recalculation request, notifying the HHA of the outcome of the review and recalculation process. The Final IPR and Preliminary Annual Report would reflect any changes noted from recalculation process. As under the original Model, we anticipate providing this response as soon as administratively feasible following the submission of the request.

We are also proposing to codify the proposed recalculation process at § 484.375(a). We invite comment on our proposals.

b. Proposed Reconsideration Process

Under the expanded Model, we propose that if we determine that the original calculation was correct and deny the recalculation request for the scores presented in the Preview Annual Report, or if the HHA otherwise disagrees with the results of a CMS recalculation as reflected in the Preliminary Annual Report, the HHA may submit a reconsideration request for the Preliminary Annual Report. We propose that an HHA may request reconsideration of the outcome of a recalculation request for its Preliminary Annual Report only. We believe that the ability to review the IPRs and submit recalculation requests on a quarterly basis provides competing HHAs with a mechanism to address potential errors in advance of receiving their Preview Annual Report. Therefore, we expect that in many cases, the reconsideration request process proposed would result in a mechanical review of the application of the formulas for the TPS and the LEF, which could result in the determination that a formula was not accurately applied.

Under this proposal, the reconsideration request and supporting documentation would be required to be submitted via instructions provided on the CMS web page within 15 calendar days of CMS' notification to the HHA contact of the outcome of the recalculation request for the Preview Annual Report. This proposed timeframe would allow a decision on the reconsideration to be made prior to the generation of the final data files containing the payment adjustment percentage for each HHA and the submission of those data files to the Medicare Administrative Contractors (MACs) to update their provider files with the payment adjustment percentage. We believe that this would allow for finalization of the annual performance scores, TPS, and annual payment adjustment percentages in advance of the application of the payment adjustments for the applicable performance year. Reconsiderations would be conducted by a CMS designated official who was not involved with the original recalculation request.

We propose that the final TPS and payment adjustment percentage be provided to competing HHAs in a Final Annual Report no later than 30 calendar days in advance of the payment adjustment taking effect to account for unforeseen delays that could occur between the time the Annual Reports are posted and the appeals process is completed.

We are also proposing to codify the proposed reconsideration process at § 484.375(b).

We are soliciting comments on these proposals.

11. Public Reporting Under the Expanded HHVBP Model

a. Background

Consistent with our discussions on public reporting under the original Model in prior rulemaking, in the CY 2020 HH PPS final rule (84 FR 60552), we finalized a policy to publicly report on the CMS website the following two points of data from the final CY 2020 Annual Report for each participating HHA in the original Model that qualified for a payment adjustment for CY 2020: (1) The HHA's TPS from performance year 5; and (2) the HHA's corresponding performance year 5 TPS Percentile Ranking. We stated that these data would be reported for each such competing HHA by agency name, city, State, and by the agency's CCN (84 FR 60552 through 60553). We refer readers to section III.B.3. of this proposed rule, where we are proposing to modify our public reporting policy for the original Model, given our proposal in section III.B.2. of this proposed rule to not use CY 2020 data to make payment adjustments for CY 2022.

Publicly reporting performance data under the expanded Model would enhance the current home health public reporting processes, as it would better inform beneficiaries when choosing an HHA, while also incentivizing HHAs to improve performance. It would also be consistent with our practice of publicly reporting performance data under other value-based initiatives such as the SNF VBP and HVBP Programs (42 CFR 413.338) (42 CFR 412.163). CMS publicly reports both facility-specific SNF VBP Program performance information (such as achievement scores, improvement scores, rankings, and incentive payment multipliers), as well as aggregate-level program performance information on the CMS website (42 CFR 413.338). Similarly, for the HVBP Program, CMS publicly reports quality measures, baseline and performance years used, domain scores, total performance scores, and aggregate payment adjustment amounts on the CMS website (42 CFR 412.163).

Publicly reporting performance data for the expanded HHVBP Model would also be consistent with other agency efforts to ensure transparency and publicly report performance data. For example, the HH QRP requires HHAs to submit data in accordance with 42 CFR 484.245(b)(1). Furthermore, section 1895(b)(3)(B)(v)(III) of the Act requires, in part, that the Secretary establish procedures for making certain HH QRP data available to the public. HHAs have been required to collect OASIS data since 1999 and to report HHCAHPS data since 2012 (64 FR 3764 and 76 FR 68577). These data are available to providers, consumers, beneficiaries, and other stakeholders on the *Care Compare* Website.

b. Proposed Public Reporting for the Expanded Model

We believe that publicly reporting performance data under the expanded HHVBP Model would be an important way of incentivizing HHAs to improve quality performance under the Model. Therefore, we are proposing to publicly report performance data for the expanded HHVBP Model beginning with the CY 2022 performance year/CY 2024 payment adjustment and for subsequent years. For all years of the expanded HHVBP Model, we propose to publicly report the following information:

- Applicable measure benchmarks and achievement thresholds for each small- and large-volume cohort.
- For each HHA that qualified for a payment adjustment based on the data for the applicable performance year—
- Applicable measure results and improvement thresholds;
- The HHA's Total Performance Score (TPS);
- The HHA's TPS Percentile Ranking; and
- The HHA's payment adjustment for a given year.

We propose to report these data by State, CCN, and agency name through a CMS website. We note that quality measure results for many of the measures proposed to be included in the expanded HHVBP Model are already currently reported on *Care Compare;* however, we are proposing to also separately publicly report applicable measure results for such measures in the expanded HHVBP Model, because the public reporting periods for the Model would differ from those used for the HH QRP public reporting on *Care Compare.* We believe this would be clear and transparent for the public. In addition, to the extent that any new measures or measures that are otherwise not included in the HH QRP and are thus not already reported on *Care Compare* are included in the expanded HHVBP Model in the future, we propose to publicly report those measure results as well.

We would also provide definitions for the TPS and the TPS Percentile Ranking methodology, as well as descriptions of the scoring and payment adjustment methodology, on the CMS website to ensure the public understands the relevance of these data points and how they were calculated. We note that this information would include a broader range of data elements than we previously finalized to publicly report for the original HHVBP Model. We are proposing a broader range of data elements for the expanded HHVBP Model for several reasons. First, this publicly reported information would align more closely with the SNF VBP and HVBP Programs, both of which publicly report a broad range of information, including measure results and payment adjustment percentages. Second, we note that measure results for those quality measures included in the HH QRP are already publicly reported on the *Care Compare* website. We believe that publicly reporting the corresponding benchmarks for all expanded Model measures (including those aligned with the HH QRP as well as measures that may not be), by cohort, and other quality performance information for the expanded HHVBP Model would further promote transparency and incentivize quality improvements under the expanded Model.

We anticipate this information would be made available to the public on a CMS website on or after December 1, 2023, the date by which we would intend to complete the CY 2022 Annual Report appeals process and issuance of the Final Annual Report to each competing HHA. For each year thereafter, we anticipate following the same approximate timeline for publicly reporting the payment adjustment for the upcoming calendar year, as well as the related performance data as previously described.

As the expanded Model's performance data would be supplemental to the Home Health Quality of Patient Care and Patient Survey Star Ratings, and does not form a part of these or other star ratings, we intend to also include a reference to the Home Health Star Ratings available on the CMS website.

We also propose to codify these proposals at § 484.355(c).

We seek public comment on these proposals.

12. Extraordinary Circumstances Exception Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances outside of their control that impact their ability to operate in the ordinary course of business for short-term, or sometimes even extended periods. The United States is currently responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as COVID–19, which creates serious public health threats that have greatly impacted the U.S. health care system, presenting significant challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events may also occur in the future that have a disruptive impact. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other extreme and uncontrollable circumstances. Such events may strain health care resources, and CMS understands that HHAs may have limited capacity to continue normal operations and fulfill expanded HHVBP Model participation requirements. In situations such as these, we believe CMS should make adjustments to the requirements of the expanded HHVBP Model to ensure the delivery of safe and efficient health care.

Therefore, generally, we propose to adopt an extraordinary circumstances exception (ECE) policy for the expanded HHVBP Model that aligns, to the extent possible, with the existing HH QRP exceptions and extension requirements at 42 CFR 484.245(c). Section 484.245(c) permits HHAs to request and CMS to grant an exception or extension from the program's reporting requirements in the event of extraordinary circumstances beyond HHAs' control.

Specifically, we are proposing that for the expanded HHVBP Model, CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. We are proposing that CMS may grant an exception as follows:

- An HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception would be available on the CMS website (*cms.gov*).
- CMS may grant an exception to one or more HHAs that have not requested an exception if: CMS determines that a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data; or if CMS determines that an extraordinary circumstance has affected an entire region or locale.

We would strive to provide our formal response notifying the HHA of our decision within 90 days of receipt of the HHA's ECE request, however, the number of requests we receive and the complexity of the information provided would impact the actual timeframe to make ECE determinations. When an ECE for HHAs in the nation, region or locale is granted, CMS would communicate the decision through routine channels to HHAs and vendors, including, but not

limited to, the PAC QRP listserv, Open Door Forum MLN Connects, and notices on the CMS *Home Health Quality Reporting Spotlight webpage.* Specific instructions for requesting exceptions or extensions would be provided on the CMS website.

We also propose to codify our ECE policy at § 484.355(d).

We seek public comment on our proposals.

B. Provisions Under the Home Health Value-Based Purchasing (HHVBP) Original Model

1. Background

The last year of data collection for the original Model ended on December 31, 2020 and the last payment adjustment year of the original Model would end on December 31, 2022. Payment adjustments are based on each HHA's TPS in a given performance year, which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS),[35] completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and select claims data elements; and (2) three New Measures for which points are achieved for reporting data. Payment adjustments for a given year are based on the TPS calculated for performance two years' prior. Under current policy for the original Model, the CY 2022 payment adjustments would be based on CY 2020 (performance year 5) performance. The maximum payment adjustment for CY 2022 is upward or downward 8 percent.

In the interim final rule with comment period that appeared in the May 8, 2020 **Federal Register** (May 2020 COVID–19 IFC) (85 FR 27553 through 27554; 85 FR 70328 through 70330), in response to the COVID–19 PHE to assist HHAs while they direct their resources toward caring for their patients and ensuring the health and safety of patients and staff, we adopted a policy to align the original Model data submission requirements with any exceptions or extensions granted for purposes of HH QRP during the COVID–19 PHE. We also established a policy for granting exceptions to the New Measures data reporting during the COVID–19 PHE, including the codification of these changes at § 484.315(b).

The original Model utilizes some of the same quality measure data that are reported by HHAs for the HH QRP, including HHCAHPS survey data. The other measures used in the original Model are calculated using OASIS data; claims-based data; and New Measure data. In response to the COVID–19 PHE, on March 27, 2020, CMS issued public guidance (*https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf*) excepting HHAs from the requirement to report HH QRP data for Q4 2019 and Q1–Q2 2020. Under our policy to align the original Model data submission requirements with any exceptions or extensions granted for purposes of the HH QRP during the COVID–19 PHE, HHAs in the nine original Model States were not required to separately report measure data for these quarters for purposes of the original Model. Specific to the original Model, we granted an exception for reporting New Measures data for the April 2020 (data collection period October 1, 2019–March 31, 2020) and July 2020 (data collection period April 1, 2020–June 30, 2020) New Measure submission periods. We further noted that HHAs may optionally submit part or all of these data by the applicable submission deadlines.

We acknowledged that the exceptions to the HH QRP reporting requirements, as well as the modified submission deadlines for OASIS data and our exceptions for the New Measures reporting requirements, may impact the calculation of performance under the original Model for performance year 5 (CY 2020). We also noted that while we are able to extract the claims-based data from submitted Medicare FFS claims, we may need to assess the appropriateness of using the claims data submitted for the period of the COVID–19 PHE for purposes of performance calculations under the original Model. We further explained that we are evaluating possible changes to our payment methodologies for CY 2022 in light of this more limited data, such as whether we would be able to calculate payment adjustments for participating HHAs for CY 2022, including those that continue to report data during CY 2020, if the overall data is not sufficient, as well as whether we may consider a different weighting methodology given that we may have sufficient data for some measures and not others. We stated that further, we are also evaluating possible changes to our public reporting of CY 2020 performance year data. We stated that we intend to address any such changes to our payment methodologies for CY 2022 or public reporting of data in future rulemaking.

2. Proposal on CY 2022 Payment Adjustments

For the reasons discussed in this section, we are proposing not to use the CY 2020 (performance year 5) data for purposes of payment adjustments under the HHVBP Model and to instead end the original Model early, with the CY 2021 payment year. Specifically, we are proposing that we would not use the annual TPS calculated using the performance year 5 data to apply payment adjustments for CY 2022 and to instead end the original Model early, such that HHAs in the nine original Model States would not have their HH PPS claims payments adjusted by the current maximum payment adjustment factor of upward or downward 8 percent in CY 2022.

In light of the data reporting exceptions under the HHVBP Model for Q1 and Q2 2020 in response to the COVID–19 PHE, as discussed previously, we reviewed available quality data from Q1 and Q2 2020 as compared to Q1 and Q2 2019 for the nine original Model States to determine whether it may be appropriate to use data from the time period during which data reporting exceptions were in place (Q1 and Q2 2020). The comparison showed a decrease of 8.9 percent in OASIS assessments. We could not directly compare HHCAHPS results from Q1 and Q2 because our data are calculated on a 12-month rolling basis. However, we also examined claims data during this same time period to determine whether volume and utilization patterns changed and observed a 20.2 percent decrease in claims-based home health stays in Q1 and Q2 2020 as compared to Q1 and Q2 2019. The change in volume and utilization was observed across time (that is, the change was not limited to a certain point of time during the Q1 and Q2 2020 time period) and within and across States. We believe these changes could be the result of the impacts of the COVID–19 PHE, including patients avoiding care or dying, reduced discharges to the home, and increased use of telehealth in lieu of in-person home health care. We also observed a 10.5 percent decrease in New Measures data submissions for Q1 and Q2 2020 as compared to Q1 and Q2 2019, consistent with what we would expect given the New Measures reporting exceptions we issued for this time period.

Based on the patterns we observed for the first two quarters of CY 2020, we do not believe it would be appropriate to utilize data from that time period to calculate a TPS for CY 2020 that would

[35] OASIS is the instrument/data collection tool used to collect and report performance data by HHAs.

be used to make payment adjustments in CY 2022. The changes in volume and utilization could skew performance assessments on quality measures for HHAs, such that the calculated TPS may not accurately reflect the quality of care provided by the HHAs. Additionally, we are concerned that because the COVID–19 PHE has not impacted all HHAs equally, implementing payment adjustments based on the impacted data for the period of the COVID–19 PHE could unfairly penalize certain HHAs.

We also considered whether to use only Q3 and Q4 CY 2020 quality measure data to calculate CY 2020 annual total performance scores for CY 2022 payment adjustments. However, we believe that using only two quarters of data may not be sufficiently representative of the care provided by the HHA during a given calendar year for purposes of calculating quality measure scores and determining payment adjustments under the Model, and could potentially disadvantage those HHAs in an area of a State more heavily affected by the pandemic in Q3 and Q4 of CY 2020. In addition, as HHAs in different States continued to be impacted by the COVID–19 PHE during the second half of CY 2020, we believe patterns of home health care may also have continued to be impacted during that timeframe, similar to the changes we observed for the Q1 and Q2 2020 time period. As more data become available from the latter half of CY 2020, we will continue to examine home health care patterns in the nine original Model States in order to determine whether the same patterns we observed in the Q1 and Q2 2020 data persisted into the latter half of the year, and to assess whether it would be appropriate to utilize such data for CY 2022 payment adjustments. Finally, we note that several commenters on the exceptions policies that we adopted in the May 2020 COVID–19 IFC requested that we not use any performance data from CY 2020 and terminate or suspend the original Model early (85 FR 70328 through 70330).

After consideration of these issues, we are proposing to not apply any payment adjustments for CY 2022 of the original HHVBP Model based on data reported in CY 2020 and to instead end the original Model early, with the CY 2021 payment adjustment year. As noted, we will continue to examine data for CY 2020 as it becomes available in order to determine whether it would be appropriate to utilize such data for CY 2022 payment adjustments, in accordance with current Model policies. We will also continue to provide HHAs with the Interim Performance Reports with CY 2020 performance data and the Annual Report with the calculated TPS and payment adjustment amount based on the CY 2020 performance data, consistent with our current policies. If we finalize our proposal, as previously discussed, we would not use the TPS calculated using the performance year 5 data to apply payment adjustments for CY 2022.

We note that if we finalize this proposal to end the original Model early, the evaluation would include the period through CY 2019 (performance year 4) and CY 2021 (payment year 4). As we are proposing to not use CY 2020 (performance year 5) data to calculate CY 2022 (payment year 5) payment adjustments, these years would not be evaluated.

We believe that our proposed policy to not use CY 2020 performance year data to determine payment adjustments under the HHVBP Model would be consistent with how other quality reporting and VBP programs are proposing to utilize data that has been significantly affected by circumstances caused by the COVID–19 PHE. In the FY 2022 Hospice proposed rule (86 FR 19755), we proposed to modify the HH QRP public display policy to display fewer quarters of data than what was previously finalized for certain HH QRP measures for the January 2022 through July 2024 refreshes (86 FR 19755 through 19764). For the January 2022 refresh, data for OASIS-based and certain claims-based measures would include Q3 2020 through Q1 2021 data. For HHCAHPS, data would cover the four quarters Q3 2020 through Q2 2021. We note that Q1 2020 and Q2 2020 data would not be included in the proposed Care Compare refresh schedule for any measures. The SNF VBP program proposed in the FY 2022 SNF PPS proposed rule (86 FR 19954) to suppress the use of the SNF readmission measure (SNFRM) for scoring and payment adjustment purposes for the FY 2022 program year. The HVBP program proposed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25469 through 25496) to suppress the use of a number of measures for the FY 2022 or FY 2023 program years for purposes of scoring and payment adjustments, along with proposals to revise the baseline periods for certain measures due to the extraordinary circumstances exception we granted in response to the COVID–19 PHE.

We are proposing to amend at § 484.305 the definition of ''*applicable percent*'' by removing paragraph (5) of the definition ((5) For CY 2022, 8 percent) to reflect our proposal not to apply any payment adjustments for FY 2022 and to end the original Model early.

We invite public comment on our proposal.

3. Public Reporting Under the Original Model

In the CY 2020 HHS PPS final rule (84 FR 60551 through 60553), we finalized a policy to publicly report on the CMS website the following two points of data from the final CY 2020 performance year 5 Annual Report for each participating HHA in the Model that qualified for a payment adjustment for CY 2020: (1) The HHA's TPS from performance year 5; and (2) the HHA's corresponding performance year 5 TPS Percentile Ranking. We stated that these data would be reported for each such competing HHA by agency name, city, State, and by the agency's CMS Certification Number (CCN). We expected that these data would be made public after December 1, 2021, the date by which we intended to complete the CY 2020 Annual Report appeals process and issuance of the final Annual Report to each HHA.

For the reasons discussed in section III.B.2. of this proposed rule, we are proposing to not use CY 2020 data for CY 2022 payment adjustments under the HHVBP Model. Consistent with this proposal, we are also proposing to modify our existing policy and not publicly report performance data for the HHAs included in the original Model. We do not believe that it would be appropriate to publicly report performance data for a time period for which HHAs would not be held financially accountable for quality, nor do we believe that reporting data for this time period would assist beneficiaries and other public stakeholders in making informed choices about HHA selection, as the patterns of care during CY 2020 may not be representative of performance under the original Model as a whole due to the COVID–19 PHE. However, as discussed in section III.A.11. of this proposed rule, we are proposing to begin public reporting for the expanded HHVBP Model with the CY 2022 performance year data, continuing for all performance years thereafter.

We are proposing to amend § 484.315 to reflect our proposal not to publicly report performance data from the CY 2020 performance year by removing paragraph (d). We seek comments on this proposal.

IV. Home Health Quality Reporting Program (HH QRP) and Other Home Health Related Provisions

A. Vaccinations for Home Health Agency Health Care Personnel

Health Care Personnel (HCP) are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe Home Health Agencies should educate and promote 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. Centers for Disease Control and Prevention. Overview of Influenza Vaccination among Health Care Personnel (*https://www.cdc.gov/flu/toolkit/long-term-care/why.htm*). Data from influenza vaccination demonstrates that provider uptake of the vaccine is associated with that provider recommending vaccination to patients, Measure Application Committee Coordinating Committee Meeting Presentation (*http://www.qualityforum.org/Project_Pages/MAP_Coordinating_Committee.aspx*). We believe HCP COVID–19 vaccination among Home Health staff could similarly increase uptake among that patient population.

B. 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 patients' 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 in the Post-Acute Care Interoperability Workgroup (PACIO) (*https://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop Fast Healthcare Interoperability Resources (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), long-term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources, including the Hospice Outcome and Patient Evaluation Assessment (HOPE) if implemented in the Hospice Quality Reporting Program through future rulemaking. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage PAC provider and health IT vendor participation as these 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 and Systematized Nomenclature of Medicine. 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 [36] 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 May 1, 2020, (hereinafter ''ONC Cures Act Final Rule'') implemented policies related to information blocking required 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 Secretary of HHS as a reasonable and necessary activity that does not constitute information blocking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.[37] For a healthcare provider (as defined in 45 CFR 171.102), specifies that the provider knows that the practice is unreasonable as well as likely to interfere with, prevent, or materially discourage access (see 45 CFR 171.103, exchange, or use of electronic health information. 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 could affect HHAs.

C. Home Health Quality Reporting Program (HH QRP)

1. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data

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

[37] 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.''

that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and further reduction of the increase by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

For more information on the policies we have adopted for the HH QRP, we refer readers to the following rules:

- CY 2007 HH PPS final rule (71 FR 65888 through 65891).
- CY 2008 HH PPS final rule (72 FR 49861 through 49864).
- CY 2009 HH PPS update notice (73 FR 65356).
- CY 2010 HH PPS final rule (74 FR 58096 through 58098).
- CY 2011 HH PPS final rule (75 FR 70400 through 70407).
- CY 2012 HH PPS final rule (76 FR 68574).
- CY 2013 HH PPS final rule (77 FR 67092).
- CY 2014 HH PPS final rule (78 FR 72297).
- CY 2015 HH PPS final rule (79 FR 66073 through 66074).
- CY 2016 HH PPS final rule (80 FR 68690 through 68695).
- CY 2017 HH PPS final rule (81 FR 76752).
- CY 2018 HH PPS final rule (82 FR 51711 through 51712).
- CY 2019 HH PPS final rule with comment period (83 FR 56547).
- CY 2020 HH PPS final rule with comment period (84 FR 60554).
- CY 2021 HH PPS final rule (85 FR 70326 through 70328).

2. General Considerations Used for the Selection of Quality Measures for the HH QRP

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and others measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule with comment (83 FR 56548 through 56550) we also finalized the factors we consider for removing previously adopted HH QRP measures.

3. Quality Measures Currently Adopted for the CY 2022 HH QRP

The HH QRP currently includes 20 measures for the CY 2022 program year, as outlined in Table 28 of the CY 2020 . HH PPS final rule (84 FR 60555).[38] [39]

TABLE 28: MEASURES CURRENTLY ADOPTED FOR THE CY 2022 HH QRP

Short Name	Measure Name & Data Source
OASIS-based	
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment	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).
Bathing	Improvement in Bathing (NQF #0174).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (NQF #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (NQF #0526).
TOH - Provider	Transfer of Health Information to Provider-Post-Acute Care[40]
TOH - Patient	Transfer of Health Information to Patient-Post-Acute Care[41]
Claims-based	
ACH	Acute Care Hospitalization During the First 60 Days of HH (NQF #0171).
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (NQF #3477)
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173).
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
HHCAHPS-based	
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (NQF #0517)[42] - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

[38] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

[39] Data collection delayed due to the COVID–19 public health emergency for the TOH-Patient and TOH-Provider.

[40] Data collection delayed due to the COVID–19 public health emergency for the TOH-Patient and TOH-Provider.

[41] *Ibid.*

[42] The HHCAHPS has five component questions that together are used to represent one NQF-endorsed measure.

4. Proposed Changes for the HH QRP

a. Proposal To Remove the Drug Education on All Medications Provided to Patient/Caregiver Measure Beginning With the CY 2023 HH QRP

The CMS Meaningful Measures framework seeks to identify the highest priorities for quality measurement and improvement and reduce where possible the burden on providers and clinicians.[43] In line with our meaningful measures initiative, we are proposing to remove the Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure from the HH QRP under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the CY 2010 HH PPS final rule (74 FR 58096), we adopted the Drug Education on all Medications Provided to Patient/Caregiver measure, an OASIS-based measure, beginning with the CY 2010 HH QRP. This process measure reports the percentage of home health quality episodes during which the patient/caregiver was instructed on how to monitor the effectiveness of drug therapy, how to recognize potential adverse effects, and how and when to report problems (at the time of or at any time since the most recent SOC/ROC assessment). This measure is calculated using data collected on OASIS Item M2016.[44]

The Drug Education on all Medications Provided to Patient/Caregiver measure has very high measure performance such that it meets our Meaningful Measure Removal Factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. The mean and median agency performance scores for this measure, from January 1, 2019 to December 31, 2019 were 97.1 percent and 99.2 percent, respectively. The mean and median agency performance score for this measure in 2010 were 85.4 percent and 97.0 percent respectively. This indicates that an overwhelming majority of patients (or their caregivers) in an HHA received drug education on all medications and demonstrated improvement over time. In addition, during the same timeframe, the 75th percentile measure score (99.9 percent) and the 90th percentile measure score (100 percent) were statistically indistinguishable from each other, meaning that measure scores do not meaningfully distinguish between HHAs.[45] Further, the truncated coefficient of variation for this measure was 0.03, suggesting that it is not useful to draw distinctions between individual agency performance scores for this measure.[46]

We note that the HH QRP also has another measure that we believe better addresses the Meaningful Measure area of medication management. The Improvement in Management of Oral Medications (#0176) measure is an NQF-endorsed outcome measure that assesses the percentage of home health quality episodes during which the patient improved in the ability to take their oral medications correctly. The OASIS item used for this measure (M2020) is currently collected at Start of Care, Resumption of Care and Discharge. The M2020 Management of Oral Medications assessment item asks about the patient's current ability to prepare and take all oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. This measure focuses on improving medication management through medication education provided to the patient. The measure performance statistics demonstrate good variation among providers and room for improvement: From January 1, 2019 to December 31, 2019, the mean and median agency performance scores for this measure was 69.4 percent and 71.9 percent, respectively; the 75th percentile measure score (79.7 percent); the 90th percentile measure score (87 percent); and the truncated coefficient of variation for this measure was 0.17. Thus, we believe this outcome measure The Improvement in Management of Oral Medications (NQF #0176) both better addresses quality issues of medication education and has better performance measure properties than the Drug Education on all Medications Provided to Patient/Caregiver process measure. Additionally, the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care measure was removed from the HH Quality of Patient Care Star Ratings in April 2019 (now Care Compare) and replaced by the Improvement in Management of Oral Medications measure (NQF #0176). The removal of Drug Education on All Medications Provided to Patient/Caregiver process measure from the HH Quality of Patient Care Star Ratings in April 2019 and replacement with the Improvement in Management of Oral Medications ensured that there was not a gap in this important topic area.

We propose to remove the Drug Education on all Medications Provided to Patient/Caregiver measure under measure removal factor 1: Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made, beginning with the CY 2023 HH QRP.

If finalized as proposed, HHAs would no longer be required to submit OASIS Item M2016, Patient/Caregiver Drug Education Intervention for the purposes of this measure beginning January 1, 2023.[47] If finalized as proposed, data for this measure would be publicly reported on Care Compare through October 1, 2023, after which it would be removed from the site.

We invite public comments on the proposal to remove Drug Education on All Medications Provided to Patient/Caregiver During All Episodes of Care measure beginning with the CY 2023 HH QRP.

b. Proposal To Replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) Measure and Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) Measure With the Home Health Within Stay Potentially Preventable Hospitalization Measure Beginning With the CY 2023 HH QRP

In the CY 2017 HH PPS final rule, we finalized a policy for replacing quality measures in the HH QRP. Specifically, we defined ''replace'' to mean adopting a different quality measure in place of a quality measure currently in the HH QRP based on one or more of the HH QRP's measure removal factors (81 FR 76754 through 76754). We are proposing to replace the Acute Care Hospital During the First 60 Days of Home Health (NQF #0171) measure and the

[43] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[44] Home Health Quality Reporting Program Measure Calculations and Reporting User's Manual *https://www.cms.gov/files/document/hh-qrp-qm-users-manual-v1-addendum.pdf.*

[45] Analysis of Home Health OASIS episodes from 2010 to 2019.

[46] The truncated coefficient of variation (TCV) is the ratio of the standard deviation to the mean of the distribution of all scores, excluding the 5 percent most extreme scores. A small TCV (≤0.1) indicates that the distribution of individual scores is clustered tightly around the mean value, suggesting that it is not useful to draw distinctions between individual performance scores.

[47] The removal or addition of an item from the OASIS instrument is subject to public comment and approval from OMB. We cannot cease reporting of this measure any earlier given the need to extend OASIS–D and submit another PRA package in January 2022 for OMB approval for OASIS–E beginning January 1, 2023.

Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) measure under measure removal factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available, with the Home Health Within Stay Potentially Preventable Hospitalization Measure beginning with the CY 2023 HH QRP.

The proposed Home Health Within Stay Potentially Preventable Hospitalization (which we will refer to as the ''PPH'' measure) measure assesses the agency-level risk-adjusted rate of potentially preventable inpatient hospitalization or observation stays for Medicare fee-for-service (FFS) beneficiaries that occur within a home health (HH) stay for all eligible stays for an agency. This proposed measure is claims-based, requiring no additional data collection or submission burden for HHAs. Our approach for defining potentially preventable hospital admissions is described in more detail in this section of this rule in the Measure Calculations section. A HH stay is defined as a sequence of HH payment episodes that are within 2 days or fewer from an adjacent payment episode. Payment episodes separated from other HH payment episodes by greater than 2 days are considered separate stays. Full details of the PPH specifications may be found at ''Proposed PPH Measure Specifications for the CY 2022 HH QRP NPRM'' at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures*.

(1) Background

Hospitalizations among the Medicare population are common, costly, and often preventable.[48] [49] [50] The Medicare Payment Advisory Commission (MedPAC) and a study by Jencks et al. estimated that 17–20 percent of Medicare beneficiaries discharged from the hospital were readmitted within 30 days. Among these hospital readmissions, MedPAC has estimated that 76 percent were considered potentially avoidable and associated with $12 billion in Medicare expenditures.[51] [52] An analysis of data from a nationally representative sample of Medicare FFS beneficiaries receiving HH services in 2004 show that HH patients receive significant amounts of acute and post-acute services after discharge from HH care.[53] Focusing on readmissions, Madigan and colleagues studied data on 74,580 Medicare HH patients and found that the 30-day rehospitalization rate was 26 percent, with the largest proportion related to a cardiac-related diagnosis (42 percent).[54] A study of data on dually eligible Medicare and Medicaid beneficiaries hospitalizations from nursing home and home and community based services waiver programs found that 39 percent of admissions were potentially avoidable.[55]

Analysis of the home health patient population has revealed some key factors associated with hospitalizations from HH including functional disability, primary diagnoses of heart disease, and primary diagnosis of skin wounds.[56] An additional beneficiary characteristic that is associated with a potential for hospitalization is the time since a beneficiary's most recent hospitalization [57] and chronic conditions such as chronic obstructive pulmonary disease and congestive heart failure.[58] How HHAs address these factors, including how HHAs address chronic conditions present before the HH stay, can determine whether beneficiaries can successfully avoid hospitalizations.[59] Understanding these factors can help HHAs design strategies to address avoidable hospitalizations.

Observation stays are also increasing nationally and can have costly financial impacts, especially for patients.[60] [61] Patients admitted for an observation stay can often be treated in the same medical units and have similar medical needs as a patient admitted for inpatient care, but the service is billed as outpatient services and does not count as a referent patient stay in the calculations of readmissions.[62] Limitation of observation stays should be a goal of HHAs along with efforts to limit inpatient hospitalizations.

We have addressed emergency department use, hospitalizations, and readmissions with a number of home health measures. Measures including the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171); Emergency Department Use without Hospitalization During the First 60 days of Home Health (NQF #0173); and the Potentially Preventable 30-Day Post-Discharge Readmission Measure for the HH QRP. The HH QRP has long sought to address hospitalization and emergency department use by home health patients since decreasing hospitalizations and use of the emergency department are important areas of quality to promote patient health outcomes and reduce unnecessary healthcare costs. Before the adoption of the Acute Care Hospitalization during the First 60 Days of Home Health (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measures, the HH QRP utilized OASIS-based iterations of these measures. In the CY 2012 HH PPS Final Rule (76 FR 68526), CMS adopted the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health claims-based measure to replace the OASIS-based Emergency Department Use Without Hospitalization measure since the claims data offered a more robust source of data for the measure. The M2300 item

[48] Friedman, B. and J. Basu. The rate and cost of hospital readmissions for preventable conditions. Med Care Res Rev, 2004. 61(2): p. 225–40.

[49] Moy, E., Chang, E., and Barret, M. Potentially Preventable Hospitalizations—United States, 2001–2009. MMWR, 2013, 62(03);139–143.

[50] Jencks, S.F., M.V. Williams, and E.A. Coleman. Rehospitalizations among Patients in the Medicare Fee-for-Service Program. New England Journal of Medicine, 2009. 360(14): p. 1418–1428.

[51] *Ibid*.

[52] MedPAC, Payment policy for inpatient readmissions, in Report to the Congress: Promoting Greater Efficiency in Medicare. 2007: Washington DC p. 103–120.

[53] Wolff, J.L., Meadow, A., Weiss, C.O., Boyd, C.M., Leff, B. Medicare Home Health Patients' Transitions Through Acute And Post-Acute Care Settings.'' *Medicare Care* 11(46) 2008; 1188–1193.

[54] Madigan, E.A., N.H. Gordon, et al. Rehospitalization in a national population of home health care patients with heart failure.'' *Health Serv Res* 47(6): 2013; 2316–2338.

[55] Walsh, E.G., J.M. Wiener, et al. (2012). ''Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and Home- and Community-Based Services waiver programs.'' *J Am Geriatric Soc* 60(5): 821–829.

[56] Lohman M.C., Cotton, B.P., Zagaria, A.B., Bao, Y., Greenberg, R.L., Fortuna, K.L., Bruce, M.L. Hospitalization Risk and Potentially Inappropriate Medications among Medicare Home Health Nursing Patients,(2017) J Gen Intern Med. 32(12):1301–1308.

[57] Hua M., Gong, M.N., Brady J., Wunsch, H. Early and late unplanned rehospitalizations for survivors of critical illness(2015) Critical Care Medicine;43(2):430–438.

[58] Dye C., Willoughby D., Aybar-Damali B., Grady C., Oran R., Knudson A. Improving Chronic Disease Self-Management by Older Home Health Patients through Community Health Coaching (2018). Int J Environ Res Public Health. 15(4): 660.

[59] Lohman M.C., Cotton, B.P., Zagaria, A.B., Bao, Y., Greenberg, R.L., Fortuna, K.L., Bruce, M.L. Hospitalization Risk and Potentially Inappropriate Medications among Medicare Home Health Nursing Patients, (2017) J Gen Intern Med. 32(12):1301–1308.

[60] Lind K.D., Noel-Miller C.M., Sangaralingham L.R., Shah N.D., Hess E.P., Morin P., Fernanda Bellolio M. Increasing Trends in the Use of Hospital Observation Services for Older Medicare Advantage and Privately Insured Patients. Med Care Res Rev. 2019. Apr;76(2):229–239.

[61] Feng Z., Wright B., Mor V. Sharp rise in Medicare enrollees being held in hospitals for observation raises concerns about causes and consequences. Health Aff (Millwood). 2012. Jun;31(6):1251–9.

[62] Sabbatini A.K., Wright B. Excluding Observation Stays from Readmission Rates—What Quality Measures Are Missing, New England Journal of Medicine, 31;378(22):2062–2065.

used to calculate OASIS-based ED Use QM was deemed to be insufficiently reliable in capturing emergency department visits. In the CY 2013 HH PPS Final Rule (77 FR 67902), CMS adopted the Acute Care Hospitalization During the First 60 Days of Home Health claims-based measure to replace the OASIS-based Acute Care Hospitalization measure since it made the determination that claims data provided a more robust data source for accurately measuring acute care hospitalizations.

The Acute Care Hospitalization During the First 60 Days of Home Health measure (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure are claims-based and were an improvement on addressing issues related to emergency department use and acute hospitalization but they also had limitations related to issues of attribution. In prior feedback from an NQF technical review panel on the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #1073), concerns were raised regarding the HHAs' ability to prevent an emergency department visit, especially for visits that do not result in a hospitalization. While some evidence suggests that care coordination and HHA engagement can impact emergency department use by patients, experts raised concerns that there were several drivers of emergency department use outside the control of an HHA that could result in an emergency department visit.[63]

Concerns related to attribution were also raised by reviewers of the Acute Care Hospitalization during the First 60 Days of Home Health when the measure was reviewed for NQF endorsement by the Steering Committee at the National Voluntary Consensus Standards for Care Coordination 2012 meetings. Reviewers acknowledged the difficulty in determining appropriate attribution for hospitalization between different providers and settings, especially when evaluating all cause hospitalization that does not require the reason for hospitalization to be related to the reason for home health care.[64]

The proposed PPH measure addresses the limitations of the Emergency Department Use Without Hospitalization During the First 60 Days of Home Health (NQF #0173) and Acute Care Hospitalization During the First 60 Days of Home Health measures (NQF #0171). First, the PPH proposed measure assesses potentially preventable observation stays instead of just emergency department use. As noted previously, observation stays are costly clinical events that require a patient to be monitored by a medical team. Limiting the occurrence of avoidable observation stays would improve patient outcomes and reduce costs. The PPH measure is focused on the subset of observation stays that technical experts determined could be addressed by HHA intervention. Similarly, the PPH proposed measure focuses on the subset of inpatient hospitalizations that could be avoided by HHA intervention. We believe the proposed PPH measure will better provide an assessment on HH quality by focusing on observation stays and acute hospitalizations that could be prevented by HHA intervention.

Several general methods have been developed to assess potentially avoidable or preventable hospitalizations and readmissions for the Medicare population. These include the Agency for Healthcare Research and Quality's (AHRQ's) Prevention Quality Indicators,[65] approaches developed by MedPAC, and proprietary approaches, such as the 3MTM algorithm for potentially preventable hospitalizations.[66] [67] [68] The existing literature addresses both hospital readmissions more broadly and potentially avoidable hospitalizations for specific settings like long-term care and highlights issues relevant to the development of potentially preventable hospitalization measures for a post-acute care setting such as home health.[69] [70]

(2) Stakeholder and Technical Expert Panel (TEP) Input

A TEP convened by our measure contractor provided recommendations on the technical specifications of this proposed measure, including the development of an approach to define potentially preventable hospital admission and observation stays for HH. TEP meetings were held in April, June, and December 2018. The TEP supported the definition of potentially preventable developed by the measure development team for both inpatient admissions and observation stays. The TEP further provided extensive guidance in refining the list of primary conditions that lead to the inpatient admission or observation stay that could be reasonably deemed preventable by HHA intervention. Details from the TEP meetings, including TEP members' ratings of conditions proposed as being potentially preventable, are available in the TEP summary report available on the CMS website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/PPH-TEP-Summary-Report-Final-101019.pdf.*

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 18 through December 16, 2019. The major comment received focused on considering the implication of implementation of the Patient Diagnosis Group Model on the specifications of this measure. CMS has undertaken a review of the implications on the new payment model on this and other claims-based QMs in the HH QRP and determined that the claims-based QMs are not adversely affected by the new model.

(3) Measure Application Partnership (MAP) Review

Our pre-rulemaking 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 the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The PPH quality measure was published in the 2019 MUC list for the HH QRP.[71]

The PPH quality measure was presented to the 2019 NQF-convened Measure Application Process (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) workgroup and the MAP

[63] National Voluntary Consensus Standards for Care Coordination 2012 Draft Technical Report. Available from *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=70600.*

[64] Ibid.

[65] Prevention Quality Indicators Overview. Available at: *https://www.qualityindicators.ahrq.gov/modules/pqi_resources.aspx.*

[66] Goldfield, N.I., McCullough, E.C., Hughes, J.S., et al. Identifying potentially preventable readmissions. Health Care Finan. Rev. 30(1):75–91, 2008. Available from *http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195042/.*

[67] National Quality Forum: Prevention Quality Indicators Overview. 2008.

[68] MedPAC: Online Appendix C: Medicare Ambulatory Care Indicators for the Elderly. pp. 1–12, prepared for Chapter 4, 2011. Available from *http://www.medpac.gov/documents/reports/Mar11_Ch04_APPENDIX.pdf?sfvrsn=0.*

[69] Gao, J., Moran, E., Li, Y.-F., et al. Predicting potentially avoidable hospitalizations. Med. Care 52(2):164–171, 2014. doi:10.1097/MLR.0000000000000041.

[70] Walsh, E.G., Wiener, J.M., Haber, S., et al. Potentially avoidable hospitalizations of dually eligible Medicare and Medicaid beneficiaries from nursing facility and home-and community-based services waiver programs. J. Am. Geriatr. Soc. 60(5):821–829, 2012. doi:10.1111/j.1532–5415.2012.03920.

[71] *https://www.cms.gov/files/document/2019muc-listclearancerpt.pdf.*

recommended conditional support for rulemaking for a single measure under consideration for the HH QRP, MUC2019–34 PPH. The MAP conditionally supported MUC2019–34 PPH, pending NQF review and endorsement. CMS clarified that it intends to eventually replace related measures, NQF 0171 Acute Care Hospitalization during the First 60 Days of Home Health and NQF 0173 Emergency Department Use (ED Use) Without Hospitalization During the First 60 days of Home Health with the PPH measure under consideration.

The MAP agreed that the PPH measure adds value to the HH QRP's measure set by adding measurement of potentially preventable hospitalizations and observation stays that may occur at any point in the home health stay. No measure in the program currently provides this information.

The MAP encouraged the consideration of including Medicare Advantage patients in future iterations of the measure. CMS is supportive of this suggestion when reliable Medicare Advantage data is available nationally. The MAP also encouraged the NQF All-Cause Admissions and Readmissions Standing Committee to consider the definition for preventable hospitalization to ensure HHAs can take adequate steps to improve these outcomes. The issue of what could be determined to be potentially preventable by HHAs was discussed extensively at multiple TEP meetings. The TEP adopted a listing of conditions that could be prevented by standard care HHAs are required to provide. The MAP encouraged CMS to provide detailed performance feedback to providers to help providers differentiate the causes of hospitalizations for quality improvement purposes. More information about the MAP's recommendations for this measure is available at *https://www.qualityforum.org/Publications/2020/02/MAP_2020_Considerations_for_Implementing_Measures_Final_Report_-_PAC_LTC.aspx.*

At the time of the MAP, the initial risk-adjustment model tested measure validity and reliability as identified in the measure specifications document, as previously provided. Testing results were very strong and showed more robust results than outcome measures previously finalized through rulemaking including the Acute Care Hospitalization During the First 60 Days of Home Health (NQF # 0171) measure and the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure.

(4) Quality Measure Calculation

We reviewed established scientific research, analyzed home health claims data, and obtained input from a technical expert panel (TEP) to develop a definition and list of conditions for which types of hospital admissions are potentially preventable. The defining of potentially preventable hospitalization relies on the previously developed conceptual framework that certain diagnoses, proper management, and care of the condition by the home health agency, combined with appropriate, clearly explained, and implemented discharge instructions and referrals, can potentially prevent a patient's admission to the hospital. On the basis of this framework, the team followed the working conceptual definition for potentially preventable hospitalizations for home health created during the development of the HH QRP measure Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program. Although not specific to PAC or hospitalizations, the team used AHRQ Prevention Quality Indicators (PQIs) and Ambulatory Care Sensitive Conditions (ACSCs) as a starting point for this work. The list of ACSCs consists of conditions for which hospitalization can potentially be prevented, given good outpatient care and early intervention.[72]

We also performed analyses on Medicare claims data to identify the most frequent diagnoses associated with admissions among home health beneficiaries, and then applied the conceptual potentially preventable hospitalization definition to evaluate whether these common conditions for a hospitalization may be considered potentially preventable. This list of conditions identified from literature and claims analysis formed the preliminary potentially preventable hospitalization definition. We grouped these conditions based on clinical rationale, and the major groups are: (1) Inadequate management of chronic conditions; (2) Inadequate management of infections; (3) Inadequate management of other unplanned events; and (4) Inadequate injury prevention.

Additional details regarding the definition for potentially preventable hospitalizations are available in the document titled ''Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures.*

This proposed PPH measure is focused on inpatient admissions or observation stays that are potentially preventable (PP) and unplanned. Thus, planned admissions are not counted in the numerator. Planned inpatient admissions and observation stays are defined largely by the definition used for the Hospital Wide Readmission [73] and Potentially Preventable Within Stay Readmission Measure for Inpatient Rehabilitation Facilities [74] measures.

The process for classifying a planned inpatient admission or observation stay is determined based on the following parameters. If an inpatient or outpatient claim contains a code for a procedure that is frequently a planned procedure, then that inpatient admission or observation stay is designated a planned inpatient admission or observation stay and is not included in the numerator. Similarly, if an inpatient or outpatient claim contains a code for a diagnosis that is frequently associated with a planned admission, then that inpatient admission or observation stay is designated to be a planned inpatient admission or observation stay and also not included in the numerator. However, the planned inpatient admission or observation stay is reclassified as unplanned if the claim also contains a code indicating one or more acute diagnoses from a specified list that is included in the criteria material described in the next sentence. Full details on the planned admissions criteria used, including the CMS Planned Readmission Algorithm and additional procedures considered planned for post-acute care, can be found in the document titled ''Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM'' at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures.*

The risk adjustment modeling estimates the effects of patient characteristics, comorbidities, and select health care variables on the probability of potentially preventable inpatient hospital admission or observation stay. More specifically, the risk-adjustment model for HHAs entails the following:

[72] Agency for Healthcare Research and Quality: AHRQ Quality Indicators—Guide to Prevention Quality Indicators: Hospital Admission for Ambulatory Care Sensitive Conditions. AHRQ Pub. No. 02–R0203. Rockville, MD. Agency for Healthcare Research and Quality, 2001.

[73] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.*

[74] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/IRF-Quality-Reporting-Program-Measures-Information-.html.*

- Demographic characteristics (age, sex, original reason for Medicare entitlement).
- Care received during prior proximal hospitalization [75] (if applicable) (including the length of the hospitalization and principal diagnoses during the prior proximal hospitalization).
- Other care received within a year of stay (including number of prior acute discharges, number of outpatient emergency department visits, number of skilled nursing visits, number of inpatient rehabilitation facility visits, number of long term care hospital visits, and comorbidities from a prior proximal hospitalization [if applicable] or other visits in the last year).

The proposed measure is calculated using a calendar year of Medicare FFS data. In addition, we propose a minimum of 20 eligible HH stays as defined in the introduction to this proposal for public reporting of the proposed measure. All HH stays during the year time window, except those that meet the exclusion criteria, would be included in the measure. The PPH observation window begins from the start of HH stay and spans to 1 day after discharge. Data from all HH stays beginning from 1/1/2016–12/31/2016 was used for the PPH measure development. For technical information about this proposed measure including information about the measure calculation, risk adjustment, and exclusions, we refer readers to our Proposed PPH Measure Specification for the CY 2022 HH QRP NPRM at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Measures*.

To meet the requirements of the CMS Meaningful Measures framework which seeks to identify the highest priorities for quality measurement and improvement and to reduce where possible the burden on providers and clinicians,[76] we are proposing to remove the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) measure and the Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure and replace them with the PPH measure. We are proposing to remove these two measures from the HH QRP beginning with the CY 2023 HH QRP under our measure removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available.

The Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measures are both claims-based and have some notable limitations related to appropriate attribution of the acute hospitalization or emergency department visit to an HHA. These measures focus on hospitalization regardless of whether a HHA could provide care that could prevent the visit whereas the proposed PPH measure addresses the limitations of these measures by focusing on inpatient admissions and observation stays that research establishes could be prevented by HHA care provided to patients they serve.

We propose to remove the Acute Care Hospitalization during the First 60 Days of Home Health (NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 days of Home Health (NQF #0173) measure and replace them with the Home Health Within-Stay Potentially Preventable Hospitalization claims-based measures beginning with the CY 2023 HH QRP.

We invite public comments on this proposal.

c. Proposed Schedule for Publicly Reporting Quality Measures Beginning With the CY 2022 HH QRP

Section 1899B(g)(1) of the Act requires, in part, that the Secretary provide for public reporting of PAC provider performance, including HHAs, on quality measures under section 1899B(c)(1) of the Act, including by establishing procedures for making available to the public information regarding the performance of individual PAC providers with respect to such measures. Section 1899B(g)(2) of the Act requires, in part, that CMS give HHAs opportunity to review and submit corrections to the data and information to be made public under section 1899B(g)(1) of the Act prior to such data being made public. Section 1899B(g)(3) of the Act requires that such procedures provide that the data and information with respect to a measure and PAC provider is made publicly available beginning not later than 2 years after the applicable specified application date applicable to such measure and provider.

In the CY 2018 HH PPS final rule, we adopted the Percent of Residents Experiencing One or More Falls with Major Injury measure beginning with the CY 2020 HH QRP under section 1899B(c)(1)(D) of the Act (82 FR 51727 through 51730). Under section 1899B(a)(2)(E)(i)(IV)(bb) of the Act, the specified application date for HH QRP measures adopted under section 1899B(c)(1)(D) of the Act is January 1, 2019; two years after this date is January 1, 2021.

We also adopted in the CY 2018 HH PPS final rule the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment measure beginning with the CY 2020 HH QRP (82 FR 51722 through 51727) under section 1899B(c)(1)(A) of the Act. Under section 1899B(a)(2)(E)(i)(I)(cc) of the Act, the specified application date for HH QRP measures adopted under section 1899B(c)(1)(A) of the Act is January 1, 2019; two years after this date is January 1, 2021.

We propose to publicly report the Percent of Residents Experiencing One or More Major Falls with Injury measure and Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) measure beginning in April 2022.

As required by section 1899B(g)(2) of the Act, to date CMS has made these two measures available for review by HHAs on the HH confidential feedback reports. The Percent of Residents Experiencing One or More Major Falls with Injury measure was added to the HHA Review and Correct Report effective 04/01/2019, and the HHA Outcome Measures Report effective 01/01/2020. The measure Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631) was added to the HHA Review and Correct Report effective 04/01/2019, and the HHA Process Measures Report effective 01/01/2020. HHAs' HH QRP measure scores for these two measures would additionally be made available for review on the HH Provider Preview Report, which would be issued in January 2022, three months in advance of the inaugural display of these measures on Care Compare.

We invite public comments on our proposed schedule to publicly display these measures.

[75] Prior proximal hospitalizations for this measure are defined as inpatient stays within 30 days prior to home health admission.

[76] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

d. Proposed Revised Compliance Date for Certain HH QRP Reporting Requirements

(1) Background

In the May 8, 2020 **Federal Register** (85 FR 27550), we published an interim final rule with comment period 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'' (which we will refer to as ''IFC–2''). In IFC–2, we delayed the compliance date for certain reporting requirements under the HH QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for HHAs to begin reporting the Transfer of Health (TOH) Information to PAC and the TOH Information to Patient-PAC measures and the requirement for HHAs to begin reporting certain Standardized Patient Assessment Data Elements to January 1st of the year that is at least one full calendar year after the end of the COVID–19 Public Health Emergency (PHE). CMS also delayed the adoption of the updated version of the Outcome and Assessment Information Set (OASIS) assessment instrument (OASIS–E) for which HHAs would report the Transfer of Health (TOH) measures and certain Standardized Patient Assessment Data Elements.

Under IFC–2, HHAs must use OASIS–E to begin collecting data on the two TOH Information measures beginning with discharges and transfers on January 1st of the year that is at least one full calendar year after the end of the COVID–19 PHE. HHAs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the OASIS–E, beginning with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) on January 1st of the year that is at least one full calendar year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was to provide relief to HHAs from the added burden of implementing an updated instrument during the COVID–19 PHE. We wanted to provide maximum flexibilities for HHAs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC–2, we believed that the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements would not have a significant impact on the HH QRP. However, the COVID–19 PHE showed the important need for these TOH Information measures and Standardized Patient Assessment Data Elements under the HH QRP. The PHE's disproportionate impact on minority populations demonstrates the importance of analyzing this impact and the needs for these populations to improve quality of care within HHAs, especially during a public health emergency.

(2) Current Assessment of HHAs

To accommodate the COVID–19 PHE, CMS has provided additional guidance and as a result HHAs have adopted new processes as well as modified existing processes. For example, HHAs currently have the option to complete what was required to be a face-to-face encounter to qualify for home health via telehealth and the completion of aspects of required comprehensive assessments via telehealth.[77] CMS also supported PAC providers, including HHAs, by providing requested flexibilities in the delivery of care in response to the PHE. In addition, we assisted providers by conducting sessions for HHAs to share best practices that agencies have identified to address many of the challenges posed by the PHE.

Based upon other flexibilities such as the examples provided and the adoption of best practices, and since finalizing IFC–2, HHAs are in a better position to accommodate reporting of the TOH measures and certain Standardized Patient Assessment Data Elements. Also, recent reports (not available at the time CMS IFC–2 was finalized) suggest that HHAs have the capacity to begin reporting the TOH measures and certain Social Determinant of Health (SDOH) Standardized Patient Assessment Data Elements.[78] Since IFC–2 was finalized, the industry has identified a growing demand for home health services and has noted their ability to meet this demand.[79] [80] [81] [82]

In addition, after evaluating the impact of the compliance date under IFC–2, feasibility around data collection by HHAs, and the support needs of providers during the COVID–19 PHE, we have determined that HHAs now have the administrative capacity to attend trainings, train their staff, and work with their vendors to incorporate the updated assessment instrument, the OASIS–E into their operations.

We now believe that based upon the processes adopted by HHAs, as previously described, the flexibilities afforded to HHAs since the beginning of the COVID–19 PHE, and the importance of the data to the HH QRP, it would be appropriate to modify the compliance date finalized in IFC–2. This may support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

3. Proposal To Collect the Transfer of Health Information to Provider-PAC Measure, the Transfer of Health Information to Patient-PAC Measure, and Certain Standardized Patient Assessment Data Elements Beginning January 1, 2023

We are proposing to revise the compliance date from IFC–2 to January 1, 2023. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the OASIS assessment instrument referred to as OASIS–E. This revised date of January 1, 2023, which is a two-year delay from this original compliance date finalized in the CY 2020 HH PPS final rule (84 FR 60557 through 60610), balances the support that HHAs needed during much of the COVID–19 PHE as CMS provided flexibilities to support HHAs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and Transfer of Health data have shown to be even more pressing with issues of inequities that the COVID–19 PHE laid bare. This

[77] *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.*

[78] *https://www.healthaffairs.org/do/10.1377/hblog20201214.543463/full/.*

[79] *https://www.hartfordbusiness.com/article/demand-for-home-health-care-surges-amid-covid-19-shifting-industry-landscape.*

[80] *https://www.forbes.com/sites/sethjoseph/2020/08/05/home-health-care-is-a-bright-light-during-covid-19-with-an-even-brighter-future/?sh=2bfa2c513891.*

[81] *https://www.wsj.com/articles/demand-for-in-home-care-rises-during-coronavirus-11588003076.*

[82] *https://www.csbj.com/premier/businessnews/healthcare/covid-19-boosts-demand-for-home-health-care/article_c65d2b4e-3b17-11eb-a46e-97a2079b065f.html.*

data that includes addressing SDOH provides information that is expected to improve quality of care for all. Consequently, we are proposing to revise the compliance date to reflect this balance and assure that this data collection begins on January 1, 2023.

As stated in the CY 2020 HH PPS final rule, CMS will provide the training and education for HHAs to be prepared for this implementation (84 FR 60554). In addition, if CMS adopts a January 1, 2023 compliance date, CMS would release a draft of the updated version of the OASIS instrument, OASIS–E, in early 2022.

Based upon our evaluation, we propose that HHAs would collect the Transfer of Health Information to Provider Post-Acute Care measure, the Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning January 1, 2023. We propose that, accordingly, HHAs would begin collecting data on the two TOH measures beginning with discharges and transfers on January 1, 2023 on the OASIS–E. We also propose that HHAs would begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the OASIS–E, with the start of care, resumption of care, and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at the start of care only) beginning on January 1, 2023.

We invite public comment on these proposals.

D. Proposed Changes to the Home Health Conditions of Participation

1. Background and Statutory Authority

Since March, 2020, CMS has issued a number of regulatory waivers in response to the COVID–19 PHE under our statutory authority granted by section 1135 of the Act. That statute permits the Secretary to waive certain statutes and regulations during a public health emergency declared by the President, in order to expand healthcare system capacity while continuing to maintain public and patient safety, and to hold harmless providers and suppliers who may be unable to comply with existing regulations after a good faith effort. Specifically, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure: Sufficient health care items and services are available to meet the needs of individuals enrolled in Medicare, Medicaid and CHIP in the emergency area during the emergency period. In such circumstances, providers can be reimbursed and exempted from sanctions under these programs (absent any determination of fraud or abuse).

We issued a variety of regulatory waivers that pertained to most CMS-certified providers and suppliers during the COVID–19 PHE, including HHAs. Sections 1861(o) and 1891 of the Act authorize the Secretary to establish the requirements that an HHA must meet to participate in the Medicare Program, and these conditions of participation (CoPs) are set forth in regulations at 42 CFR part 484. We waived selected requirements for HHAs within part 484 for the duration of the PHE. While some of these waivers simply delay certain administrative deadlines, others directly impact the provision of patient care. We have identified waivers related to the requirements for the supervision of home health aides at § 484.80(h)(1) and (2) that we believe would be appropriate as permanent policy. These proposed changes and their respective background information are discussed in detail.

In addition, in order to implement section 115 of Division CC of the CAA 2021, we are proposing to modify the requirements for the home health initial assessment visit and comprehensive assessment. This statutorily-required modification allows an occupational therapist to complete the initial and comprehensive assessments for Medicare patients when occupational therapy is ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility. This would only be permitted if skilled nursing services have not been ordered.

2. Provisions of the Proposed Regulations

We propose the following revisions to the HHA CoPs.

a. Home Health Aide Supervision

Home health aides deliver a significant portion of direct home health care. Ensuring that aide services are meeting the patient's needs is a critical part in maintaining safe, quality care. At § 484.80(h)(1) and (2), we differentiate aide supervision requirements based on the level of care required by the patient. Aides caring for a patient receiving skilled care from nurses or therapists must currently have an on-site supervisory visit every 14 days, while aides caring for a patient who is not receiving skilled care must have an on-site supervisory visit every 60 days.

We believe the current 14-day on-site supervisory visit requirement when a patient is receiving skilled services is an important component to assessing the quality of care and services provided by the HHA aide, and to ensure that aide services are meeting the patient's needs. Currently, the regulations require that the 14-day supervisory assessment be conducted by the registered nurse (RN) or other appropriate skilled professional who is familiar with the patient, the patient's plan of care and the written care instructions as described in 484.80(g). However, we believe it is important to permit HHA's to complete this assessment virtually, in the rare circumstance that an onsite visit cannot be coordinated within the 14-day time period.

We propose that HHAs be permitted to use interactive telecommunications systems for purposes of aide supervision, on occasion, not to exceed 2 virtual supervisory assessments per HHA in a 60-day period. We are proposing to revise the language at § 484.80(h)(1)(i) to require that if a patient is receiving skilled care (that is, skilled nursing, physical or occupational therapy, or speech language pathology services), the home health aide supervisor (RN or other appropriate skilled professional) must complete a supervisory assessment of the aide services being provided, either onsite (that is, an in person visit) or by using interactive telecommunications systems to ensure aides are furnishing care in a safe and effective manner, no less frequently than every 14 days. The home health aide does not need to be present during this supervisory assessment. As outlined in regulation at § 484.80(h)(4), the home health aide supervisory assessment is required to ensure that the aide is furnishing care in a safe and effective manner, such as: Following the patient's plan of care for completion of tasks assigned to the home health aide; maintaining an open communication process with the patient, representatives, caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring the patient's rights. We are proposing the define interactive telecommunications systems as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. The use of interactive telecommunications systems for the aide supervisory assessment must not exceed 2 virtual supervisory

assessments per HHA in a 60-day period, regardless of the number of aides or patients associated with a given HHA. If the supervising individual notes an area of concern during the 14-day supervisory assessment, the supervising individual must make an on-site in-person visit to the location where the patient is receiving care while the aide is performing care, in order to observe and assess the aide as required at § 484.80(h)(1)(ii) and (iii).

While we are proposing to allow this flexibility, we expect that in most instances, the HHAs would plan to conduct the 14-day supervisory assessment during an on-site, in person visit, and that the HHA would use interactive telecommunications systems option only for unplanned occurrences that would otherwise interrupt scheduled in-person visits. Examples of circumstances in which a scheduled on-site in-person visit may not be able to be rescheduled timely within the 14-day window could include a severe weather occurrence, a patient requests to change the date of the scheduled visit, or unexpected staff illness or absence on the planned day for the visit.

We are not proposing changes to the requirements for annual aide assessments at § 484.80(h)(1)(iii). In addition to the regularly-scheduled 14-day supervisory assessment and as-needed observation visits for aides providing care to patients receiving skilled services, HHAs are required to make an annual on-site, in person, visit to a patient's home to directly observe and assess each home health aide while he or she is performing patient care activities. The HHA is required to observe each home health aide annually with at least one patient.

We are also proposing revisions to the supervisory assessment requirements for aides providing care to patients who are not receiving skilled care services. At § 484.80(h)(2), we currently require that if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care from such aide. Such visits must occur at least once every 60 days in order to observe and assess each home health aide while he or she is providing care. This supervisory visit must be performed by a RN because these patients are not otherwise receiving HHA services from other professionals, such as therapists. We continue to receive feedback that this requirement is overly burdensome for the patient and the HHA if multiple home health aides provide care to the same patient. For instance, if a patient has three different home health aides providing care, the nurse is currently required to observe and assess each of the three home health aides while the aide is giving care to the patient. This circumstance would entail three separate nursing supervision visits on the same patient every 60 days. While we believe that the HHA's observation of an aide providing direct care to the patient is important to ensure quality, requiring a patient to receive three separate supervision visits every 60 days may be onerous on the patient and the HHA.

We propose to maintain the first part of this requirement, that the registered nurse must make a visit in person every 60 days, but would remove the requirement that the RN must directly observe the aide in person during those visits. We would accomplish this by removing the language from 42 CFR 484.80(h)(2) that states, ''in order to observe and assess each home health aide while he or she is performing care,'' and replacing it with ''to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs''. In addition, we propose to further revise the requirement to state that the home health aide would not need to be present during this visit. We believe that these proposed revisions from an on-site (direct) observation of each aid while performing care to an indirect supervision visit to assess the adequacy of the aide care plan, the patient's perception of services provided, and hear any concerns from the patient; may better support the patients' needs by allowing for open communication between the nurse and patient. If a deficiency in the aide services are assessed, the agency must conduct and the home health aide must complete, retraining and a competency evaluation for the deficient and all related skills.

In order to ensure appropriate RN supervision of HHA aides caring for patients who are not receiving skilled services, we propose to add a new requirement to 42 CFR 484.80(h)(2) that would require the RN to make a semi-annual on-site visit to the location where a patient is receiving care in order to directly observe and assess each home health aide while he or she is performing care. This semi-annual in-person assessment would occur twice yearly for each aide, regardless of the number of patients cared for by that aide.

Supervisory visits allow professionals to evaluate whether aides are providing appropriate care as ordered by the patient's plan of care. When RNs or qualified professionals identify a deficiency in aide services, § 484.80(h)(3) requires that the agency conduct, and the home health aide complete, retraining and a competency evaluation related to the deficient skill(s).

We propose to maintain this requirement at 484.80(h)(3), but to modify it by adding ''and all related skills.'' We believe that when a deficient area(s) in the aide's care are assessed and verified by the RN, additional related competencies may reflect deficient practice areas that should be addressed. For example, if the patient informs the nurse that they almost fell when the aide was transferring them from bed to a chair, the nurse should assess the aide's technique for transferring a patient in other circumstances beyond transfer to a chair, such as transferring from a bed to bedside commode or to a shower chair.

We request public comment on our proposed changes to allow virtual supervisory assessments of home health aides for patients receiving skilled care at § 484.80(h)(1)(i), and for the proposed changes to supervision, competency assessment, and retraining for aides providing care to patients receiving all levels of HHA care. We especially welcome comments from patients and caregivers who have experienced virtual supervisory assessments of home health aides during the PHE.

b. Permitting Occupational Therapists To Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

On December 27, 2020, the CAA, 2021 was signed into law. Division CC, section 115 of the CAA 2021 requires CMS to permit an occupational therapist to conduct the initial assessment visit and complete the comprehensive assessment under the Medicare program, but only when occupational therapy is on the home health plan of care with either physical therapy or speech therapy and skilled nursing services are not initially on the plan of care. We are proposing to conforming regulation text changes at § 484.55(a)(2) and (b)(3), respectively to implement this provision.

Currently, the requirement at § 484.55(a)(2) states, ''When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled

professional.'' We are proposing to add additional language that allows the occupational therapist to complete the initial assessment for Medicare patients when skilled nursing is not initially on the plan of care, but occupational therapy is ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility as a need for occupational therapy alone would not initially establish program eligibility under the Medicare home health benefit (see section 1814(a)(2)(c) and 1835(a)(2)(A) of the Act). Similarly, at § 484.55(b)(3), we are proposing to modify our regulatory language to allow an occupational therapist to complete the comprehensive assessment for Medicare patients when ordered with another qualifying rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility and when skilled nursing is not initially part of the plan of care. It should be noted that the statutory requirements for establishing Medicare program eligibility have not changed. Therefore, only the need for skilled nursing, physical therapy or speech language pathology services can initially establish eligibility for Medicare home health care. However, occupational therapy can maintain eligibility for Medicare home health care after the need for skilled nursing, physical therapy, and speech language pathology services have ceased (see sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act).

c. Adequacy of Aide Staffing

As stated earlier, ensuring that aide services are meeting the patient's needs is a critical part in maintaining safe, quality care. However, in 2019 MedPAC reported that between 1998 and 2017 home health visits declined by 88 percent. CMS seeks information about the adequacy of aide staffing and requests comments on the following:

- Whether home health agencies employ or arrange for (under contract) home health aides to provide aide services;
- The number of home health aides per home health agency (both directly employed and under contract), and whether the number has increased or decreased over the past 5–10 years;
- The average number of aide hours per beneficiary with aide service ordered on the plan of care;
- The effect of the public health emergency on the ability of HHAs to employ home health aides or arrange for (under contract) the provision of home health aide services.

V. Home Infusion Therapy Services: Annual Payment Updates for CY 2022

A. Home Infusion Therapy Payment Categories

Section 5012 of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255), which amended sections 1834(u), 1861(s)(2) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit, effective January 1, 2021. The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education not otherwise covered under the durable medical equipment benefit, remote monitoring, and monitoring services for the provision of home infusion therapy furnished by a qualified home infusion therapy supplier.

Section 50401 of the Bipartisan Budget Act (BBA) of 2018 amended section 1834(u) of the Act by adding a new paragraph (7) that established a home infusion therapy services temporary transitional payment for eligible home infusion suppliers for certain items and services furnished in coordination with the furnishing of transitional home infusion drugs beginning January 1, 2019. The temporary transitional payment began on January 1, 2019 and ended the day before the full implementation of the home infusion therapy services benefit on January 1, 2021.

For the full implementation of the home infusion therapy services benefit on January 1, 2021, CMS established a unit of single payment for each infusion drug administration calendar day in the individual's home. In accordance with section 1834(u)(1)(A)(ii) of the Act, a unit of single payment must be established for different types of infusion therapy, taking into account variation in utilization of nursing services by therapy type. Furthermore, section 1834(u)(1)(B)(ii) of the Act required that the single payment amount reflect factors such as patient acuity and complexity of drug administration. In the CY 2020 HH PPS final rule with comment period (84 FR 60628), we finalized our proposal to maintain the three payment categories that were utilized under the temporary transitional payments for home infusion therapy services. The three payment categories group home infusion drugs by J-code based on therapy type. The single payment amount for each payment category varies by utilization of nursing services and reflects patient acuity and complexity of drug administration, and; therefore, ultimately reflects variations in infusion drug administration services. Payment category 1 comprises certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; and chelation drugs. Payment category 2 comprises subcutaneous infusions for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions. Payment category 3 comprises intravenous chemotherapy infusions and other highly complex intravenous infusions. We are not proposing to make any changes to the three payment categories in CY 2022.

The categories and associated J-codes can be found in the MLN Matters article entitled ''Billing for Home Infusion Therapy Services On or After January 1, 2021'' (MM11880).[83] This list will be updated as new drugs and biologicals are added to the DME LCD and determined to be ''home infusion drugs.'' The list of home infusion drugs and their respective payment categories do not need to be updated through rulemaking when a new drug is added to the DME LCD for External Infusion Pumps (L33794).[84]. The payment category may be determined by the DME MAC for any subsequent home infusion drug additions to the DME LCD for External Infusion Pumps (L33794)[85] as identified by the following NOC codes: J7799 (Not otherwise classified drugs, other than inhalation drugs, administered through DME) and J7999 (Compounded drug, not otherwise classified). Payment category 1 would include any appropriate subsequent intravenous infusion drug additions, payment category 2 would include any appropriate subsequent subcutaneous infusion drug additions, and payment category 3 would include any appropriate subsequent intravenous chemotherapy or other highly complex drug or biologic infusion additions.

Section 1861(iii)(3)(C) of the Act defines a home infusion drug as a parenteral drug or biological administered intravenously or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME. Such term does not include the following: (1) Insulin

[83] Billing for Home Infusion Therapy Services On or After January 1, 2021 (MM11880). *https://www.cms.gov/files/document/mm11880.pdf.*

[84] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794.*

[85] Local Coverage Determination (LCD): External Infusion Pumps (L33794). *https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794.*

pump systems; and (2) a self-administered drug or biological on a self-administered drug (SAD) exclusion list. Division CC, section 117 of CAA 2021 amended section 1861(iii)(3)(C) of the Act so that the previously detailed SAD exclusion in the definition of home infusion drug would not apply to a self-administered drug or biological on a SAD exclusion list if such drug or biological was included as a transitional home infusion drug under subparagraph (A)(iii) of section 1834(u)(7), and was identified by a HCPCS code described in subparagraph (C)(ii) of such section.

In the CY 2021 HH PPS final rule (85 FR 70337), we stated that Hizentra®, a subcutaneous immunoglobulin, was not included in the definition of ''home infusion drugs'' under the benefit beginning January 1, 2021, because it was listed on a SAD exclusion list maintained by the Medicare Administrative Contractors (MACs). We also stated that if it is removed from all the SAD exclusion lists, Hizentra® could be added to the home infusion drugs list in the future. After publication of the CY 2021 HH PPS Final Rule on November 4, 2020, CAA 2021 was signed into law on December 27, 2020. Division CC, section 117 of CAA 2021 amended the definition of home infusion drugs in Section 1861(iii)(3)(C) of the Act as previously noted.

Hizentra® was included as a transitional home infusion drug according to the definition of such drug in section 1834(u)(7)(A)(iii) of the Act, and was identified by a HCPCS code (J1559) described in subparagraph (C)(ii) of such section of the Act. Therefore, consistent with the statutorily amended definition of ''home infusion drug'', the home infusion therapy services related to the administration of Hizentra® are covered under payment category 2 under both the temporary transitional payment from 2019 to 2020, and the permanent benefit beginning January 1, 2021.

It is important to note that the list of home infusion drugs is maintained by the DME MACs, and the drugs or their respective payment categories for purposes of the home infusion therapy services benefit do not need to be updated through rulemaking every time a new drug is added to the DME LCD for External Infusion Pumps (L33794). For these routine updates, CMS will implement such changes through the subregulatory change request process.

B. Payment Adjustments for CY 2022 Home Infusion Therapy Services

1. Home Infusion Therapy Geographic Wage Index Adjustment

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. In the CY 2020 HH PPS final rule with comment period (84 FR 60629) we finalized the use of the geographic adjustment factor (GAF) to adjust home infusion therapy payments for differences in geographic area wages rates based on the location of the beneficiary. We remind stakeholders that the GAFs are a weighted composite of each Physician Fee Schedule (PFS) localities work, practice expense (PE) and malpractice (MP) expense geographic practice cost indices (GPCIs) using the national GPCI cost share weights. The periodic review and adjustment of GPCIs is mandated by section 1848(e)(1)(C) of the Act. At each update, the proposed GPCIs are published in the PFS proposed rule to provide an opportunity for public comment and further revisions in response to comments prior to implementation. The GPCIs and the GAFs are updated triennially with a 2-year phase in and were last updated in the CY 2020 PFS final rule. The next full update to the GPCIs and the GAFs will be in the CY 2023 PFS proposed rule. For CY 2022, there will be changes to the GAF values for the majority of localities located in California because CY 2022 is the last year of a 5-year incremental transition for the majority of the California localities implemented in 2017 in accordance with the Protecting Access to Medicare Act of 2014 (PAMA 2014). The CY 2022 PFS proposed GAFs will be available on the PFS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched.*

In the CY 2020 HH PPS final rule with comment period (84 FR 60629) we stated that the application of the GAF would be budget neutral so there is no overall cost impact by applying a budget-neutrality factor. We propose to continue this practice and apply the GAF budget-neutrality factor to the home infusion therapy service payment rates whenever there are changes to the GAFs in order to eliminate the aggregate effect of variations in the GAFs. For CY 2022, the GAF standardization factor would equal the ratio of the estimated national spending total using the CY 2021 GAF to the estimated national spending total using the CY 2022 GAF. Estimates of national spending totals would use home infusion therapy benefit utilization data for CY 2020. The CY 2022 GAF was not available in time for this proposed rule. We will calculate the CY 2022 GAF standardization factor that will be used in updating the payment amounts for CY 2022 and we will include this information in a forthcoming change request that would be issued to implement the CY 2022 home infusion therapy services payment amounts. The CY 2022 GAF values will be posted as an addendum on the PFS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched* under the supporting documentation section of the CY 2022 Medicare Physician Fee Schedule Final Rule and posted on the Home Infusion Therapy Billing and Rates web page.[86]

2. Consumer Price Index

Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections we are required to increase the single payment amount from the prior year (that is, CY 2021) by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding year, reduced by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity. Section 1834(u)(3) of the Act further states that the application of the productivity adjustment may result in a percentage being less than 0.0 for a year, and may result in payment being less than such payment rates for the preceding year.

The CPI–U for the 12-month period ending with June of the preceding year is not available at the time of this proposed rulemaking. The CPI–U for the 12-month period ending in June of 2021 and the corresponding productivity adjustment will be updated in the final rule.

3. Initial and Subsequent Visit Adjustment

In the CY 2020 HH PPS final rule with comment period (84 FR 60627), we finalized our policy that the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home will be increased by the average difference between the PFS

[86] Home Infusion Therapy Services Billing and Rates. *https://www.cms.gov/medicare/home-infusion-therapy-services/billing-and-rates.*

amounts for E/M existing patient visits and new patient visits for a given year, resulting in a small decrease to the payment amounts for the second and subsequent visits, using a budget neutrality factor. We remind stakeholders that effective January 1, 2021 there were changes to the office/outpatient E/M visit code set (CPT codes 99201 through 99215) used to calculate the initial and subsequent visit payment amounts for home infusion therapy. These changes were adopted from the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) and include the deletion of code 99201 (Level 1 office/outpatient visit, new patient), and new values for CPT codes 99202 through 99215. The initial visit percentage increase will still be calculated using the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year; however, only new patient E/M codes 99202 through 99205 were used in the calculation, as the final policy indicates that the calculation is based on the relative difference between the average of the new and existing patient E/M codes. For CY 2021, the initial visit percentage increase was calculated using the average difference between the CY 2021 PFS amounts for office/outpatient E/M existing patient visits (99211 through 99215) and the CY 2021 PFS amounts for office/outpatient E/M new patient visits (99202 through 99205). In the CY 2021 HH PPS final rule (85 FR 70340), we estimated a 19 percent increase in the first visit payment amount and a 1.18 percent decrease in subsequent visit amounts based on the average difference between the CY 2021 proposed PFS E/M codes amounts for new and existing patients. The percent increase remained 19 percent for the first visit payment amount and the percent decrease remained 1.18 percent for subsequent visit amounts using the final PFS E/M rates for new and existing patients.

However, Division N, section 101 of CAA 2021 added section 1848(t)(1) of the Act, which applied a 3.75 percent increase in PFS payment amounts only for CY 2021.[87] Division CC, section 113 of CAA 2021 also delayed the implementation of an add-on E/M code G2211 until CY 2024. Because the PFS relative value units (RVUs) are budget neutral, this delay in the implementation of the add-on code changed the RVUs for all codes under the PFS, including the E/M codes used to calculate the home infusion therapy service payment initial visit percent increase. The updated RVUs and conversion factor after the changes implemented by the CAA 2021 were used to recalculate the CY 2021 payment amounts for home infusion therapy services, and the percent difference used to calculate the initial visit percentage increase. As a result, the initial home infusion therapy service visits increase was updated to 20 percent and the decrease for subsequent visits was updated to 1.3310. We note that the change in the percent increase for initial visits was driven by the delay of the code G2211. While the updated payment amounts (after the changes implemented by the CAA 2021) for the office/outpatient E/M codes were used to recalculate the initial visit increase, removing the 3.75 percent does not impact the average difference between the office/outpatient E/M codes for new patient visits and existing patient because the increase was applied equally. Therefore, after removing the adjustment, the percent increase remains 20 percent for the initial visit payment amounts and a 1.3310 percent decrease for all subsequent visit payment amounts.

In the CY 2021 final rule (85 FR 70298, 70339) we also stated that we would increase the payment amounts for each of the three payment categories for the first home infusion therapy visit by the qualified home infusion therapy supplier in the patient's home by the average difference between the PFS amounts for E/M existing patient visits and new patient visits for a given year. Section 1834 (u)(3) of the Act requires the rates from the previous year to be updated by the percentage increase in the CPI–U for the 12-month period ending in June of 2021 reduced by a productivity adjustment beginning in 2022. Therefore, CMS is to update the established payment rates for CY 2021 by the percentage increase in the CPI–U reduced by the productivity adjustment without recalculating the percent difference each year using the updated values for the PFS E/M codes for CY 2022 payment purposes. For CY 2022, we are proposing to maintain the 20 percent increase calculated for the initial home infusion therapy service visits and the 1.3310 percent decrease calculated for subsequent visits after implementation of the changes mandated by the CAA 2021, which we previously noted did not impact these percentages. Table 34 shows the updated E/M visit codes and the final unadjusted PFS payment amounts (without the 3.75 percent increase implemented by the CAA 2021) for CY 2021, for both new and existing patients, used to determine the increased payment amount for the first visit. We invite comments on our proposal to maintain the percentages calculated for initial and subsequent home infusion therapy service visits calculated after implementing the changes mandated by the CAA 2021.

[87] Medicare Learning Network Connects ''Special Edition: Physician Fee Schedule Update'' (Jan 7, 2021). *https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf.*

TABLE 34: AVERAGE PERCENT DIFFERENCE BETWEEN PFS E/M CODES FOR NEW AND EXISTING PATIENTS

New Patient E/M Code	Unadjusted CY 2021 PFS Rates	Existing Patient E/M Code	Unadjusted CY 2021 PFS Rates	Percent Difference
		99211	$22.20	NA
99202	$71.30	99212	$54.82	30%
99203	$109.64	99213	$89.12	23%
99204	$163.79	99214	$126.46	30%
99205	$216.25	99215	$176.57	22%
Total	$560.98		$469.17	20%

Source: The unadjusted CY 2021 PFS rates are calculated based on the updated CY 2021 RVUs which were recalculated after the removal of code G2211 and the unadjusted PFS Conversion Factor which is calculated by removing the 3.75 percent increase in PFS payments for CY 2021. The RVUs used in CY 2021 Final Rule are taken from CY 2021 PFS Final Rule Addendum B, version dated December 29, 2020 (Available at: https://www.cms.gov/files/zip/cy-2021-pfs-final-rule-addenda-updated-12292020.zip; Accessed on 3/17/2021).

C. CY 2022 Payment Amounts for Home Infusion Therapy Services

As noted previously, Division N, section 101 of CAA 2021 amended added section 1848(t)(1) of the Act, which applied and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payment amounts only for CY 2021.[88] For CY 2022, CMS will remove the 3.75 percent increase from the PFS amounts used to establish the CY 2021 home infusion therapy payment rates and use the unadjusted CY 2021 rates for these CY 2022 payment amounts will be updated for CY 2022 in accordance with section 1834(u)(3) of the Act using the percentage increase in the CPI–U for the 12-month period ending in June of 2021 reduced by the productivity adjustment, adjusted for MFP.

The final home infusion therapy 5-hour payment amounts will be released in a forthcoming change request CR and posted on the Home Infusion Therapy Billing and Rates web page.[89] For more in-depth information regarding the finalized policies associated with the scope of the home infusion therapy services benefit and conditions for payment, we refer readers to the CY 2020 HH PPS final rule with comment period (84 FR 60544).

[88] Medicare Learning Network Connects ''Special Edition: Physician Fee Schedule Update'' (Jan 7, 2021). *https://www.cms.gov/files/document/2021-01-07-mlnc-se.pdf.*

[89] Home Infusion Therapy Services Billing and Rates. *https://www.cms.gov/medicare/home-infusion-therapy-services/billing-and-rates.*

VI. Medicare Provider and Supplier Enrollment Changes

A. Background—Provider and Supplier Enrollment Process

1. General Discussion

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that helps prevent unqualified and potentially fraudulent individuals and entities from being able to enter and inappropriately bill Medicare. Since 2006, we have taken various steps via rulemaking to outline our enrollment procedures. These regulations are generally incorporated in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.570 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

One such requirement (outlined in § 424.510) is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) (hereafter occasionally referenced as ''Medicare contractor'' or simply ''contractor'') the appropriate enrollment application, typically the Form CMS–855 (OMB Control No. 0938–0685). The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System) collects important information about the provider or supplier; such data includes, but is not limited to, general identifying information (for example, legal business name), licensure and/or certification data, and practice locations. After receiving the provider's or supplier's initial enrollment application, CMS or the MAC will review and confirm the information thereon and determine whether the provider or supplier meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse.

As already mentioned, over the years we have issued various final rules pertaining to provider and supplier enrollment. These were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers and suppliers: (1) Engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent therewith, and as further discussed in section VI.B. of this proposed rule, we propose several changes to our existing provider enrollment regulations in this proposed rule.

2. Legal Authorities

There are two principal sources of legal authority for our proposed provider enrollment provisions. Section 1866(j) of the Act provides specific authority with respect to the enrollment process for providers and suppliers. Sections 1102 and 1871 of the Act furnish general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

B. Proposed Provisions

1. Effective Dates

We propose to codify in regulation certain effective date practices discussed in CMS Publication 100–08, Program Integrity Manual (PIM) (or in other subregulatory guidance). We believe that incorporating these topics into 42 CFR part 424 would furnish needed clarification and allow the provider community to furnish public comments thereon.

a. Effective Date of Billing Privileges

Section 424.520 outlines the effective date of billing privileges for provider and supplier types that are eligible to enroll in Medicare. Paragraph (d) thereof sets forth the applicable effective date for physicians, non-physician practitioners (NPP), physician organizations, NPP organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers. This effective date is the later of: (1) The date of filing of a Medicare enrollment application that a Medicare contractor subsequently approved; or (2) the date that the provider or supplier first began furnishing services at a new practice location. In a similar vein, § 424.521(a) States that the seven previously mentioned provider and supplier types can retrospectively bill for services when they have met all program requirements (including State licensure requirements), and services were provided at the enrolled practice location for up to—

- Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Pub. L. 100–707, enacted November 23, 1988), 42 U.S.C. 5121–5206 (Stafford Act), precluded enrollment in advance of providing services to Medicare beneficiaries.

In essence, these provisions afford the affected providers and suppliers a limited ability to ''back bill'' for services furnished before the contractor approves the provider's or supplier's application. This reflects CMS' recognition that circumstances can prevent a provider's or supplier's enrollment prior to the furnishing of Medicare services. With this in mind, CMS, under the applicable PIM guidance, had applied the effective date policies in §§ 424.520(d) and 424.521(a) to the following additional supplier types: (1) Part B hospital departments; (2) Clinical Laboratory Improvement Amendment labs; (3) intensive cardiac rehabilitation facilities; (4) mammography centers; (5) mass immunizers/pharmacies; (6) radiation therapy centers; (7) physical therapists; (8) occupational therapists; and (9) speech language pathologists.

For the reasons previously discussed, we propose to add these nine supplier types to the scope of §§ 424.520(d) and 424.521(a). The specific regulatory changes would be as follows.

First, the title and opening paragraph of § 424.520(d) currently reads: *(d)* Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers. The effective date for billing privileges for physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers is the later of . . . . Rather than add the nine aforementioned supplier types to the seven provider and supplier types already listed within this language (thus making the latter unnecessarily long), we propose to shorten and simplify the language to state that the effective date of billing privileges for the provider and supplier types identified in paragraph (d)(2) of this section is the later of the following. Consistent with this proposed change, we would also do the following:

- Redesignate existing § 424.520(d)(1) and (2) as, respectively, new § 424.520(d)(1)(i) and (ii).
- List the 16 previously referenced provider and supplier types as new § 424.520(d)(2)(i) through (xvi).

Second, the title of § 424.521 would be changed from ''Request for payment by physicians, non-physician practitioners, physician and non-physician organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers'' to ''Request for payment by certain provider and supplier types.''

Third, the opening language of current § 424.521(a) reads ''Physicians, non-physician practitioners, physician and non-physician practitioner organizations, ambulance suppliers, opioid treatment programs, and home infusion therapy suppliers may retrospectively bill for services when the physician, non-physician practitioner, physician or non-physician organization, ambulance supplier, opioid treatment program, or home infusion therapy supplier—.'' We propose to revise this language to state that the providers and suppliers identified in paragraph (a)(2) of this section may retrospectively bill for services when the provider or supplier.

Fourth, we propose to—

- Redesignate existing § 424.521(a)(1) and (2) as, respectively, new § 424.521(a)(1)(i) and (ii); and
- List the 16 aforementioned provider and supplier types as new § 424.521(a)(2)(i) through (xvi).

b. Effective Dates of Reassignments and Form CMS–855O Enrollments

(1) Reassignments

A Form CMS–855R application (OMB Control No. 0938–0685) must be completed for any individual supplier (reassignor) who wishes to reassign his or her Part B benefits to an eligible entity or individual (reassignee) under § 424.80. (This frequently occurs when, for example, a physician joins a group practice and, as a condition of her employment, reassigns the payments for the services she furnishes on behalf of the group practice to the latter.) If the reassignor is not enrolled in Medicare, he or she must complete a Form CMS–855I (OMB Control No. 0938–0685) application as well as a Form CMS–855R.

Under the applicable PIM guidance, CMS applied the basic principles of §§ 424.520(d) and 424.521(a) to Form CMS–855R reassignments when establishing the effective date of the latter. As with §§ 424.520(d) and 424.521(a), this subregulatory policy was intended to account for instances where the supplier may have been unable to submit a Form CMS–855R application earlier than what occurred. To codify this into regulation, we propose to add a new § 424.522, the title of which would state: ''Additional effective dates.'' Paragraph (a) of § 424.522 would specify that a reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS–855R is submitted if all applicable requirements during that period were otherwise met.

(2) Practitioner Enrolling Solely To Order or Certify Via Form CMS–855O

Under § 424.507, a physician or other eligible professional (as that term is

defined in § 424.506(a)) who orders or certifies covered—(1) Imaging services; (2) clinical laboratory services; (3) durable medical equipment, prosthetics, orthotics, and supplies; and/or (4) home health services must be enrolled in or validly opted-out of Medicare for the resulting claim to be eligible for payment. There are situations where the physician or other eligible professional indeed wishes to enroll to order and/or certify these services and/or items but is not seeking Medicare billing privileges. He or she will accordingly complete the Form CMS–855O (''Medicare Enrollment Application: Enrollment for Eligible Ordering, Certifying and Prescribing Physicians and Eligible Professionals; OMB Control #: 0935–1135). CMS or MAC approval of this application does not grant billing privileges but only permits the individual to order/certify the aforementioned services and/or items.

Although the effective date provisions in §§ 424.520(d) and 424.521(a) do not (and indeed could not) apply to Form CMS–855O enrollments because no billing privileges or payments are involved, the PIM states that a Form CMS–855O enrollment effective date is the date on which the Medicare contractor received the application (as opposed to, for instance, the date the contractor approves the application). This permitted the individual to order/certify these services and items for a limited period prior to enrollment. To codify this in regulation, we propose to state the following in new § 424.522(b): ''The effective date of a Form CMS–855O enrollment is the date on which the Medicare contractor received the Form CMS–855O application if all other requirements are met.''

We are also proposing several effective date provisions relating to the provider enrollment concept of deactivation. These are addressed within the larger deactivation discussion in section VI.B.3. of this proposed rule.

2. Rejections and Returns

a. Background and Distinction

Per § 424.525(a), CMS may reject a provider's or supplier's enrollment application for any of the following reasons:

- The prospective provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information.
- The prospective provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.
- The prospective institutional provider (as defined in § 424.502) does not submit the application fee (in accordance with § 424.514) in the designated amount or a hardship waiver request with the Medicare enrollment application at the time of filing.

The PIM outlines additional factual situations in which an application could have been rejected.

The purpose of the rejection policy is to encourage the provider or supplier to: (1) Fully and completely submit all required information (and any required documentation) with their enrollment application; and (2) promptly respond to any contractor requests for clarification regarding the application. If a provider's or supplier's application is rejected (for example, because the provider or supplier did not correct an error on its application per the contractor's request), the contractor notifies the provider or supplier via letter accordingly. The letter outlines, among other things, the reason for the rejection under § 424.525(a) and informs the provider or supplier that the latter must submit a new application.

The PIM also discusses the return of provider enrollment applications. In general, an application has been returned when one of the return grounds outlined in the PIM applied. These grounds typically involve situations where the provider's or supplier's submission constitutes, in essence, a non-application. This is different from a rejected application in that the latter: (1) Does not automatically involve an invalid submission yet the application, for instance, failed to include certain information or documentation or contains erroneous data; and (2) can be remedied prior to any rejection via the provider's or supplier's submission of a corrected, revised, supplemented, or complete application.

We recognize that there has been uncertainty within the provider community regarding the difference between application rejections and returns as well as the grounds for both actions. To clarify these issues, we propose to revise § 424.525 and to add a new § 424.526.

b. Proposed Rejection and Return Policies

(1) Rejections

The three previously mentioned reasons in § 424.525(a) for rejecting an application are currently designated as, respectively, paragraphs (a)(1), (a)(2), and (a)(3). We propose to include the following ten rejection scenarios (almost all of which had been identified as reasons for rejection in the PIM) within the larger § 424.525(a)(1) category. This means that rejection in these ten situations would only occur if the provider or supplier failed to comply with the requirements of (a)(1) (for instance, furnishing correct and complete data) within the 30-day period stated therein. We believe that incorporating these situations within the scope of § 424.525(a)(1) would ease the burden on providers and suppliers because they would be given time to correct the application's deficiencies. (We note that, under the current and proposed versions of § 424.525, CMS may reject an application but is not required to.)

The scenarios in question would be designated as § 424.525(a)(1)(i) through (x) and are as follows:

- The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, social security number, contact information, and practice location information).
- The application is unsigned or undated.
- The application contains a copied or stamped signature.
- The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.
- The application is signed by a person unauthorized to do so under 42 CFR part 424, subpart P.
- For paper applications, the required certification statement is missing.
- The paper application is completed in pencil.
- The application is submitted via fax or email when the provider or supplier was not otherwise permitted to do so.
- The provider or supplier failed to submit all of the forms needed to process a Form CMS–855 reassignment package within 30 days of receipt. (For example, a newly enrolling physician who will be reassigning her benefits to a group practice submits a Form CMS–855R application but fails to submit an accompanying Form CMS–855I application.)
- The provider or supplier submitted the incorrect Form CMS–855 application. (For example, the provider submitted a Form CMS–855B when a Form CMS–855A application (Medicare Enrollment Application; Institutional Providers; OMB # 0938–0685) was required.)

We reiterate our belief, and it has been our experience, that these rejection

scenarios in proposed new § 424.525(a)(1)(i) through (x) involve situations where the provider or supplier can remedy (and, in many cases, has remedied) their application submission fairly expeditiously. (For instance, an unsigned or improperly signed application can be corrected with the proper signature.) Grounds for application returns, on the other hand, involve situations that cannot be remedied without an entirely new application submission because the initial submission was invalid or otherwise could not be accepted and processed. With both rejections and returns, however, there are no appeal rights.

Existing § 424.525(b), (c), and (d) address various operational aspects of our rejection policy. We are not proposing to revise them. However, and to clarify the scope of § 424.525, we propose in new § 424.525(e) that § 424.525 applies to all CMS provider enrollment application submissions, including: (1) Form CMS–855 initial applications, change of information requests, changes of ownership (CHOWs), revalidations, and reactivations; (2) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement; OMB # 0938–0626) submissions; (3) Form CMS–20134 submissions; and (4) any electronic or successor versions of the forms identified in § 424.525(e)(1) through (3). This is to help ensure that the provider or supplier furnishes a correct and complete submission regardless of the type of CMS enrollment form involved. Concomitant with this change, we propose to remove the word ''prospective'' from §§ 424.525(a)(1), (a)(2), (a)(3), and (b). This will clarify that these three rejection grounds apply to enrolled providers and suppliers and not simply prospective enrollees.

(1) Returns

For reasons already explained, we propose in new § 424.526(a) that the following situations constitute grounds for CMS' or the contractor's return of the provider's or supplier's application to the provider or supplier. These grounds, which were discussed in the PIM, would be designated as § 424.526(a)(1) through (13). The opening language of paragraph (a) would state, however, that CMS or the Medicare contractor ''may'' return the application in the following instances but is not required to:

- The provider or supplier sent its paper Form CMS–855, Form CMS–588, or Form CMS–20134 application to the incorrect Medicare contractor for processing. (For example, the application was sent to Contractor X instead of Contractor Y.)
- The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. (This does not apply to (1) providers and suppliers submitting a Form CMS–855A application, (2) ambulatory surgical centers, or (3) portable x-ray suppliers.
- The seller or buyer in a change of ownership submitted its Form CMS–855A or Form CMS–855B application more than 90 days prior to the anticipated date of the sale.
- The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from (1) a provider or supplier submitting a Form CMS–855A application, (2) an ambulatory surgical center, or (3) a portable x-ray supplier.
- The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.
- The provider or supplier submitted an initial enrollment application prior to the expiration of their existing reenrollment bar under § 424.535 or reapplication bar under § 424.530(f).
- The application is not needed for (or is inapplicable to) the transaction in question.
- The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.
- A Medicare Diabetes Prevention Program (MDPP) supplier submitted an application with a coach start date more than 30 days in the future. (That is, the application lists an MDPP coach who will commence his or her services beginning at least 31 days after the date the Medicare contractor receives the application.)
- The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.
- The provider or supplier submits an application that is an exact duplicate of an application that (1) has already been processed or (2) is currently being processed or is pending processing.
- The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 application that is outdated and/or has been superseded by a revised version.
- The provider or supplier submits a Form CMS–855A or Form CMS–855B initial enrollment application followed by a Form CMS–855A or Form CMS–855B CHOW application. If the Medicare contractor:

++ Has not yet made a recommendation for approval concerning the initial application, both applications may be returned in this scenario.

++ Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the CHOW application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS–855A or Form CMS–855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS–855A or Form CMS–855B application.

We note that several of these return grounds involve situations where the application is submitted prematurely. CMS and its contractors had previously encountered numerous instances where, for instance, a Part B supplier would submit an enrollment application well over 9 months before: (1) The practice location effective date that the supplier listed on their application; and/or (2) the date on which the supplier planned to begin furnishing services or otherwise commence operations. Just as frequently, providers and suppliers would submit initial enrollment applications well in advance of the expiration of their: (1) Appeal rights following the denial of their previous application submission; and/or (2) Medicare reenrollment bar following a revocation. This essentially required contractors to hold and track the submitted application for many months until the application could be processed at a time closer to the supplier's commencement date. To alleviate contractors of this burden, the PIM identified various dates before which the provider or supplier could not submit an application.

We also propose in § 424.526 to explain certain operational components of our return policy. First, we propose in § 424.526(b) that a provider or supplier may not appeal a return of their enrollment application. (Section 424.525(d) contains a similar provision for rejections.) Since, as previously stated, we believe the situations outlined in proposed § 424.526(a) essentially involve the submission of a non-application, we do not believe appeal rights would be appropriate. Second, we propose to effectively duplicate proposed § 424.525(e) in new proposed § 424.526(c). This would clarify the types of enrollment applications and transactions to which § 424.526 would apply.

3. Deactivation

(a) Background

Regulatory policies regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or ''reactivated'') upon the submission of information required under § 424.540. As stated in § 424.540(c), deactivation is intended to protect the provider or supplier from the misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments.

A deactivated provider or supplier is not revoked from Medicare and remains enrolled in the program; also, per § 424.540(c), deactivation does not impact the provider's or supplier's existing provider or supplier agreement. However, the provider's or supplier's ability to bill Medicare is halted pending its compliance with § 424.540's requirements for reactivation. Deactivation, in short, is a less severe action than a revocation but one significant enough to encourage providers and suppliers to maintain compliance with enrollment requirements.

There are currently three grounds for deactivation under § 424.540(a), listed as, respectively, paragraphs (a)(1), (a)(2), and (a)(3):

- The provider or supplier does not submit any Medicare claims for 12 consecutive calendar months.
- The provider or supplier does not report a change in its enrollment information within 90 calendar days of the change. (Changes in ownership or control must be reported within 30 calendar days.)
- The provider or supplier does not furnish complete and accurate information and all supporting documentation within 90 calendar days of receipt of notification from CMS to submit a revalidation application in accordance with § 424.515. (In addition, § 424.550(b) permits deactivation if the prospective new owner in a CHOW fails to submit a new enrollment application containing information concerning the new owner within 30 days of the CHOW. CMS may also deactivate in a CHOW situation if: (1) An incomplete CHOW application is submitted containing material omissions; or (2) CMS has information that makes it question whether the provider agreement will be transferred to the new owner.)

To reactivate one's billing privileges, § 424.540(b) states that the provider or supplier must: (1) Recertify that their enrollment information currently on file with Medicare is correct and furnish any missing information as appropriate; or (2) submit a complete Form CMS–855 application if required by CMS.

We constantly examine the effectiveness of our deactivation processes from both a program integrity and a provider impact perspective. Based on this monitoring, we believe that several revisions to § 424.540 are needed. In general, these changes are meant to, as applicable: (1) Clarify existing policies; (2) incorporate certain subregulatory discussions into § 424.540 to afford stakeholders an opportunity for public comment; (3) give CMS greater flexibility in its payment safeguard activities; and (4) reduce provider and supplier burden.

(b) Grounds for Deactivation

As already mentioned, deactivation is a CMS action that is more moderate than a revocation. Unlike the latter, a deactivation neither involves the imposition of a reenrollment bar nor is considered a final adverse action under § 424.502. It constitutes, in a sense, a middle ground between CMS imposing a revocation that (under the circumstances) could be an overly harsh measure and CMS taking no action at all, thus potentially leaving a program integrity risk intact. In this manner, it enables us to avoid an ''all-or-nothing'' situation.

We believe that expanding this flexibility to include additional grounds for deactivation would help CMS achieve a proper medium that protects the Medicare program without burdening providers and suppliers with an unwarranted revocation and the consequences thereof. It would, at CMS' discretion, allow for a third option (besides revocation and non-action) that might be the fairest and most appropriate given the facts involved. Accordingly, we propose a number of changes to § 424.540(a) and (b).

First, existing paragraph (a) contains an opening clause followed by the three existing deactivation reasons, codified as paragraphs (a)(1), (a)(2), and (a)(3). We propose to add several new deactivation grounds as paragraphs (a)(4) through (a)(8); respectively, they would be as follows:

- The provider or supplier is not in compliance with all enrollment requirements in Title 42.
- The provider's or supplier's practice location is non-operational or otherwise invalid.
- The provider or supplier is deceased.
- The provider or supplier is voluntarily withdrawing from Medicare.
- The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

Proposed reasons (a)(4) and (a)(5) reflect existing bases for revocation. We propose including them within § 424.540 because, depending on the specific circumstances in question, they sometimes involve relatively modest instances of non-compliance that the provider or supplier can correct. Reasons (a)(6), (a)(7), and (a)(8) are merely technical, non-substantive deactivation grounds referenced in subregulatory guidance; a deactivation in these situations had simply ''closed'' the provider's or supplier's enrollment without the need for a revocation.

Second, we propose to revise § 424.540(b)(1) to state: ''In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.'' The addition of the language concerning compliance is primarily meant to account for our addition of § 424.540(a)(4) and (5). The recertification of enrollment data alone would not be enough for providers and suppliers deactivated under either of these grounds; they (or, as applicable, their practice location(s)) must also have resumed compliance. However, this change would also clarify that compliance with all enrollment requirements would be required for providers and suppliers deactivated under § 424.540(a)(1), (a)(2), or (a)(3) to be reactivated. (We recognize that § 424.540(b)(1) would be largely inapplicable to proposed deactivation grounds § 424.540(a)(6), (7), and (8) because the provider or supplier has effectively departed the Medicare program.)

In new paragraph (d)(1)(i), and consistent with existing policy, we propose to specify that except as provided in paragraph (d)(1)(ii) of this section, the effective date of a deactivation is the date on which the deactivation is imposed under this section. In paragraph (d)(1)(ii), we propose that CMS may apply a retroactive deactivation effective date—based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)—in the following instances (which would include our proposed new deactivation grounds, discussed previously):

++ For deactivation reasons (a)(2), (3), and (4), the effective date would be

the date on which the provider or supplier became non-compliant (for example, the expiration of the period in which the provider was required to report a change in its enrollment information).

++ For deactivation reason (a)(5), the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

++ For deactivation reason (a)(6), the date of death of the provider or supplier.

++ For deactivation reason (a)(7), the date on which the provider or supplier voluntarily withdrew from Medicare.

++ For deactivation reason (a)(8), the date of the sale.

(c) Payment Prohibition

We propose in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). We recognize that the PIM has permitted retroactive payment (once the provider or supplier is reactivated) for services furnished during the period of deactivation; current subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation. After careful reflection, however, we believe that the most sensible approach from a program integrity perspective is to prohibit such payments altogether. In our view, a provider or supplier should not be effectively rewarded for its non-adherence to enrollment requirements (for example, failing to respond to a revalidation request or failing to timely report enrollment information changes) by receiving payment for services or items furnished while out of compliance; indeed, the prospect of a payment prohibition could well spur providers and suppliers to avoid such non-compliance. We believe proposed § 424.540(e) would not only be an important payment safeguard in this regard but also would: (1) Clarify this important issue (which has created some confusion within the provider community); and (2) allow the public to furnish feedback on the topic.

(d) Additional Revisions

We also propose three additional clarifications to the deactivation provisions in § 424.540. First, the opening sentence of § 424.540(c) states that deactivation ''is considered an action to protect the provider or supplier from misuse of its billing number and to protect the Medicare Trust Funds from unnecessary overpayments.'' While this sentence is true, we previously mentioned other purposes of deactivation, such as encouraging providers and suppliers to remain compliant with Medicare requirements. Given the multiple rationales for the deactivation process, we believe the first sentence of § 424.540(c) is too restrictive and propose to remove it. (The existing second sentence of § 424.540(c) would remain intact and comprise the whole of revised paragraph (c).)

Second, and as alluded to previously, the concluding sentence of existing § 424.540(a)(2) states that changes in ownership or control ''must be reported within 30 calendar days as specified in §§ 424.520(b) and 424.550(b).'' We propose to clarify that our existing deactivation authority under § 424.540(a)(2) applies to both the changes that must be reported within 90 days and those within 30 days. Consequently, we would delete the existing version of this paragraph and state that deactivation is permitted if the provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title. Our use of the word ''title'' would account for provisions in Title 42 (such as those in § 424.516) that require certain provider and supplier types to report such changes within the timeframes specified therein.

Third, under the applicable PIM guidance, the effective date of a reactivation is generally the date on which the Medicare contractor received the application that was processed to completion. To clarify this policy in regulation, we propose to add it as new § 424.540(d)(2) with one modification, in that the word ''completion'' would be replaced with ''approval.'' This would make clear that the contractor would have to actually approve the application (rather than merely complete the processing thereof) in order for the reactivation to become effective.

6. HHA Capitalization

Under §§ 489.28(a) and 424.510(d)(9), an HHA entering the Medicare program—including a new HHA resulting from a change of ownership if the latter results in a new provider number being issued—must have sufficient funds (known as initial reserve operating funds) available: (1) At the time of application submission; and (2) at all times during the enrollment process, to operate the HHA for the 3-month period after the Medicare contractor conveys billing privileges (exclusive of actual or projected accounts receivable from Medicare). This means that the HHA must also have available sufficient initial reserve operating funds during the 3-month period following the conveyance of Medicare billing privileges.

To enable CMS or the Medicare contractor to verify compliance with the requirements of §§ 489.28(a) and 424.510(d)(9), the HHA must submit adequate proof of the availability of initial reserve operating funds. Section 489.28(d) states that such proof must include, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, ''accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA.'' With respect to borrowed funds, § 489.28(e) states that if such funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a statement similar to the bank/financial institution officer attestation referenced in § 489.28(d). CMS has recently learned that several national bank chains are no longer providing these attestation statements, thus hindering the ability of HHAs to comply with § 489.28(d) or (e). To remedy this, we propose to insert the phrase ''(if the financial institution offers such attestations)'' after the term ''financial institution'' as used § 489.28(d) and (e).

7. HHA Changes of Ownership

Section 424.550(b) states that if there is a change in majority ownership of an HHA by sale within 36 months after the effective date of the HHA's initial enrollment in Medicare or within 36 months after the HHA's most recent change in majority ownership, the HHA's provider agreement and Medicare billing privileges do not convey to the new owner (hereafter occasionally referenced as the ''36-month rule''). Instead, the prospective provider/owner of the HHA must: (1) Enroll in Medicare as a new (initial) HHA; and (2) obtain a state survey or accreditation. We had seen situations where an HHA submitted an initial enrollment application, underwent a Sate survey, became Medicare-enrolled, and then promptly sold (or ''flipped'') the HHA (via our change of ownership regulations in § 489.18) to an unqualified party. This was problematic because the latter would not have to undergo a new State survey. By effectively imposing a 36-month ''waiting period'' for HHA changes in majority ownership under § 424.550(b), we have been able to stem such instances of ''flipping'' or, if an HHA sale does occur within this timeframe,

fully scrutinize the new owner via a State survey and the initial provider enrollment process. This is particularly important given, as previously mentioned, the heightened program integrity risks that HHAs have historically presented.

However, we recognize in § 424.550(b) that there are instances where qualified HHAs change their ownership without any intent to circumvent a State survey or initial enrollment. Therefore, we created several exceptions in which the 36-month rule does not apply. One exception (identified in § 424.550(b)(2)(i)) is that the HHA has submitted 2 consecutive years of full cost reports; we believe this circumstance indicates that the HHA has been legitimately and fully functioning for an extended period, thus negating to some extent our concern that the HHA may be engaged in ''flipping.'' There has been uncertainty within the provider community as to whether this particular exception applies only to the 2-year cost report period after initial enrollment or also to 2-year cost report periods after the HHA's previous change in majority ownership. In assessing whether an HHA has been operational and providing services for 2 consecutive years for purposes of the 36-month rule, we see no appreciable difference between a period following initial enrollment and one succeeding a change in majority ownership. We accordingly propose to revise the first sentence of § 424.550(b)(2)(i) to specify that the HHA submitted 2 consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. (The second sentence of § 424.550(b)(2)(i), which clarifies that low utilization or no utilization cost reports do not qualify as full cost reports for purposes of § 424.550(b)(2)(i), would remain intact.)

VII. Survey and Enforcement Requirements for Hospice Programs

A. Background

Hospice care, as referenced in our regulations at § 418.3, means a comprehensive set of services described in section 1861(dd)(1) of the Act. These services are identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care that is individualized and person-centered. Hospice care is a comprehensive, holistic approach to treatment that recognizes the impending death of a terminally ill individual and warrants a change in the focus from curative care to palliative care for the relief of pain and symptom management. Medicare regulations at § 418.3 define ''palliative care'' as patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, emotional, social, and spiritual needs and facilitating patient autonomy, access to information, and choice. Palliative care that is patient-centered and individualized is at the core of hospice philosophy and care practices, and is a critical component of the Medicare hospice benefit.

The goal of hospice care is to help terminally ill individuals continue life with minimal disruption to normal activities while remaining primarily in the home environment. A hospice program uses an interdisciplinary approach to deliver medical, nursing, social, psychological, emotional, and spiritual services through a collaboration of professionals and other caregivers, to make the beneficiary as physically and emotionally comfortable as possible.

As referenced in hospice program regulations at § 418.22(b)(1), to be eligible for Medicare hospice program services, the patient's attending physician (if any) and the hospice program medical director must certify that the individual is ''terminally ill,'' as defined in section 1861(dd)(3)(A) of the Act and our regulations at § 418.3. The individual has a medical prognosis that his or her life expectancy is 6 months or less if the illness runs its normal course. Under the Medicare hospice program benefit, the election of hospice program care is a patient choice and once a terminally ill patient elects to receive hospice care, a hospice interdisciplinary group (IDG) is essential in the seamless provision of primarily home-based services.

Hospice programs must comply with applicable civil rights laws,[90] including section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act, under which covered entities must take appropriate steps to ensure effective communication with patients and patient care representatives with disabilities, including the provisions of auxiliary aids and services. Additionally, they must take reasonable steps to ensure meaningful access for individuals with limited English proficiency, consistent with Title VI of the Civil Rights Act of 1964. Further information about these requirements may be found at: *http://www.hhs.gov/ocr/civilrights.*

[90] Hospices are also subject to additional Federal civil rights laws, including the Age Discrimination Act, section 1557 of the Affordable Care Act, and conscience and religious freedom laws.

1. Medicare Participation and Survey Activity

Sections 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), and 1861(dd) of the Act, and the implementing regulations in 42 CFR part 418, establish eligibility requirements, payment standards, and procedures; define covered services; and delineate the conditions a hospice program must meet to be approved for participation as a provider in the Medicare program. Part 418, subpart G, provides for a per diem payment based on one of four prospectively-determined rate categories of hospice care (routine home care, continuous home care, inpatient respite care, and general inpatient care), based on each day a qualified Medicare beneficiary is under hospice care (once the individual has elected). This per diem payment is meant to cover all of the hospice services and items needed to manage the beneficiary's care, as required by section 1861(dd)(1) of the Act.

Section 1864(a) of the Act authorizes the State survey agencies (SAs) or other appropriate local agencies, under an agreement with CMS, to perform surveys of health care providers and suppliers to assess their compliance with the applicable Medicare conditions. There are several types of surveys conducted, including initial surveys (to receive initial certification), recertification surveys (to maintain certification), complaint surveys (to investigate complaints), and surveys for validation of the results of Accrediting Organization (AO) surveys. Only the SA or CMS may survey certain provider types because a CMS-approved AO option does not exist for their type, while others cannot be surveyed by SAs in accordance with the statute but can only be accredited by a CMS-approved AO (such as providers of the technical component of advanced diagnostic imaging). Based on the SA recommendations from survey findings, CMS determines whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

2. CMS Requirements for AOs Approved To Deem Hospice Programs

Section 1865(a) of the Act allows most health care facilities to demonstrate their compliance with the Medicare conditions through accreditation by a CMS-approved program of an AO,

instead of being surveyed by SAs for certification. Currently CMS-approved accreditation programs for facilities under section 1865(a) of the Act include Ambulatory Surgical Centers (ASCs); Hospitals; Critical Access Hospitals (CAHs); Home Health Agencies (HHAs); Hospices; Outpatient Physical Therapy (OPT) facilities; End-Stage Renal Disease (ESRD) facilities; and Rural Health Clinics (RHCs). This is referred to as ''deeming'' accreditation. This is because CMS-approved AOs are recognized by the Secretary as having programs with accreditation standards that meet or exceed those of Medicare. Therefore, any provider or supplier that is accredited by an AO under a CMS-approved accreditation program is deemed by CMS to have also complied with the applicable Medicare conditions or requirements. Accreditation by an AO is generally voluntary on the part of the providers and suppliers, as they have the choice to seek accreditation from an approved AO or seek Medicare certification through the SA.

CMS is responsible for—(1) providing continuous oversight of the AOs' accreditation programs to ensure that providers or suppliers accredited by the AOs meet the required Medicare conditions or requirements; (2) ensuring that the AOs have formalized procedures to determine whether the health care facilities deemed under their accreditation programs meet the AO's accreditation standards (which must meet or exceed the applicable Medicare program requirements); and (3) ensuring that the AO's accreditation standards and practices for surveying providers and suppliers meet or exceed the Medicare conditions and practices for approving.

The current regulations at § 488.4 set forth the general provisions for CMS-approved accreditation programs for providers and suppliers. The requirements at § 488.5 set out application and re-application procedures for national AOs that seek to obtain CMS approval of their accreditation programs, often called ''deeming authority.'' These regulations task CMS with the responsibilities of approval and oversight of the AOs' accreditation programs.

As of March 2021, there are three AOs with CMS-approved hospice accreditation programs: Accreditation Commission for Health Care, Inc. (ACHC), Community Health Accreditation Partner (CHAP), and The Joint Commission (TJC). These three AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half.

B. Provisions of the Proposed Rule

1. Overview

Division CC, section 407 of the CAA 2021, amended Part A of Title XVIII of Act to add a new section 1822 to the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements. There are nine new survey and enforcement provisions. The law requires public reporting of hospice program surveys conducted by SAs and AOs, as well as enforcement actions taken as a result of these surveys, on CMS's website in a manner that is prominent, easily accessible, searchable and readily understandable format. It also removes the prohibition at section 1865(b) of the Act of public disclosure of hospice surveys performed by AOs, requiring that AOs use the same survey deficiency reports as SAs (Form CMS–2567, ''Statement of Deficiencies'' or a successor form) to report survey findings. The law requires programs to measure and reduce inconsistency in the application of survey results among all surveyors. The law requires the Secretary to provide comprehensive training and testing of SA and AO hospice program surveyors, including training with respect to review of written plans of care. The statute prohibits SA surveyors from surveying hospice programs for which they have worked in the last 2 years or in which they have a financial interest, requires hospice program SAs and AO to use a multidisciplinary team of individuals for surveys conducted with more than one surveyor (to include at least one registered nurse (RN)), and provides that each SA must establish a dedicated toll-free hotline to collect, maintain, and update information on hospice programs and to receive complaints. Finally, the law directs the Secretary to create a Special Focus Program (SFP) for poor-performing hospice programs, sets out authority for imposing enforcement remedies for noncompliant hospice programs, and requires the development and implementation of a range of remedies as well as procedures for appealing determinations regarding these remedies. These enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program. These remedies include civil money penalties (CMPs), suspension of all or part of payments, and appointment of temporary management to oversee operations.

The provision requiring a new hospice program hotline is effective 1 year after the CAA 2021 enactment (that is, December 27, 2021). Most other provisions are effective on October 1, 2021, including the following—the requirement to use multidisciplinary survey teams, the prohibition of conflicts of interest, expanding CMS-based surveyor training to AOs, and the requirement for AOs with CMS-approved hospice accreditation programs to begin use of the Form CMS–2567 (or a successor form). The public disclosure of survey information and the requirement to develop and implement a range of enforcement remedies is effective no later than October 1, 2022. The other provisions in the legislation were effective upon enactment of the CAA 2021.

In this proposed rule, we are proposing a comprehensive strategy to enhance the hospice program survey process, increase accountability for hospice programs, and provide increased transparency to the public. Our goals include: (1) Maintaining the public trust through addressing conflicts of interest and improving survey transparency; (2) addressing inconsistency within the survey process through training and survey team composition and use of common hospice program deficiency reporting mechanisms; and (3) ensuring hospice programs are held accountable for addressing identified health and safety issues. The statutory requirements outlined in the CAA 2021 will address CMS' goals and are in the best interest of patients who receive care in Medicare-participating hospice programs.

We propose to add new subparts M and N to 42 CFR part 488 to implement the CAA 2021 requirements. Subpart M would provide survey and certification processes while subpart N would provide the enforcement remedies for hospice programs with deficiencies that are not in compliance with Medicare participation requirements. The proposed enforcement remedies for hospice programs with deficiencies are similar to the alternative enforcement sanctions available for HHAs with deficiencies. We propose to amend § 488.2 and § 488.28, where appropriate, to include the reference to hospice program. In addition, we propose to amend terminations and appeals requirements in 42 CFR parts 489 and 498 based on the proposed enforcement remedies.

2. Subpart A—General Provisions

a. Statutory Basis (§§ 488.2 and 498.1)

The CAA 2021 amended Part A of title XVIII of the Act to add section 1822 of the Act on hospice program survey

and enforcement procedures. We propose to amend the requirement at § 488.2 and at § 498.1 to include this statutory reference to hospice program services.

b. Application and Re-Application Procedures for National Accrediting Organizations (§ 488.5)

We propose at § 488.5(a)(4)(x) to require the AOs, as part of a hospice program AO's application and reapplication process, to submit a statement acknowledging that the AO will include a statement of deficiencies (that is, the Form CMS–2567 or a successor form) to document findings of the hospice program Medicare CoPs under section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

Currently, the regulations under § 488.5 do not require AOs to utilize the same forms as SA surveyors when documenting survey findings of noncompliance. Specifically, § 488.5(a)(4)(ii) in part states that AOs with CMS-approved programs must submit documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting Federal Medicare surveys for the same provider or supplier type. . . . Therefore, AOs are not required to and do not utilize the Form CMS–2567 to report their survey findings, nor do they use the same software system used by SAs to capture the information. Each of the three AOs with CMS-approved hospice program deeming authority, has a unique software system that is proprietary to the organization and develops a unique survey report for their deemed hospice organizations. These systems are platforms for AO/client communication as well as document storage and are unique to the AOs standards and process, which may meet or exceed those of CMS. The AO's survey reports, provided to hospice program clients, set out the deficiencies related to CMS requirements, as well as any additional AO standards combined into one report.

The Form *CMS–2567 Statement of Deficiencies and Plan of Correction* [91] is the legal, documentary basis for how SAs and CMS Federal surveyors note findings of compliance or noncompliance (deficiencies) resulting from an inspection of Medicare-participating providers and suppliers. Our regulations at § 488.18 require that SAs document all deficiency findings on a statement of deficiencies, which is the Form CMS–2567.

Additionally, §§ 488.26 and 488.28 further delineate how findings must be recorded and that CMS prescribed forms must be used. The Form CMS–2567 is used to state concisely and in a standard format, whether or not any deficiencies were identified during a survey, including the evidence to support each finding. Following the survey, the provider/supplier will use the form to document their plan for correcting the identified deficiencies.

The completed Form CMS–2567 exists in PDF format and is also compiled by the CMS Automated Survey Processing Environment (ASPEN) survey software, which is the current national database, designed to help SAs collect and manage healthcare provider data. CMS is in the process of transitioning the ASPEN software system to a new, web-based internet Quality Improvement and Evaluation System (iQIES).[92] In mid-2021, CMS will begin transitioning to the new software system on a program-specific implementation schedule, starting with HHAs. It may take several years to fully transition all programs to the new technology platform, and CMS will continue to evaluate documentation needs, make necessary system adjustments with each program that transitions, and train surveyors on system use.

Currently, AOs are able to access the online PDF version of the Form CMS–2567 but do not have access to the CMS ASPEN system, as this software was only designed and distributed for use by SAs and CMS employees. CMS and the AOs must therefore determine the systems process for the inclusion and subsequent collection of the Form CMS–2567 as part of all deemed hospice program surveys completed by AOs. CMS already requires all AO survey reports to identify the comparable Medicare CoPs for each finding of noncompliance with accreditation standards (§ 488.5(a)(4)(iv)). Therefore, in order to meet the new statutory requirement for hospice program AOs to also use the Form CMS–2567 (or a successor form), each of the three CMS-approved hospice program AOs must now develop a way to incorporate this form into their data systems.

As required by § 488.5(a)(11)(ii), AOs submit their survey findings to CMS. The database, *Accrediting Organization System for Storing User Recorded Experiences* (ASSURE), is currently used by AOs to provide CMS with survey data from its deemed facilities. The ASSURE system requires the AO to match its specific survey findings and comparable AO standards to the Medicare conditions or requirements by uploading a spreadsheet text file, designed based on the data fields in the system, or by manually inputting the information. At this time, the ASSURE system does not and cannot develop a statement of deficiencies Form CMS–2567, as ASPEN does for SA surveyors, because ASSURE was designed to capture survey details and findings based on the requirements for AOs at § 488.5.

CMS is currently assessing the systems revisions needed for each of the three database options (ASPEN, ASSURE, and iQIES) to determine if one of the systems could be a future vehicle for hospice program AOs to document their survey findings in the same manner as SAs and subsequently have those forms easily captured by CMS for reporting purposes. Since ASPEN and ASSURE are nearing the end of their lifecycle, as CMS transitions to iQIES, it may not be prudent for CMS to invest resources and redistribute funding intended to update the future system to update legacy systems. At this time, it is most important for AOs to develop a way of incorporating the Form CMS–2567 into their documentation systems. As their systems are proprietary, CMS is unable to tell the AOs exactly how to incorporate the Form CMS–2567, but we will work with the AOs to determine how their version can be submitted to CMS via electronic data exchange.

Separately from the systems issues, the existing format of the Form CMS–2567 must be modified, as it does not currently have a place for the name of the AO that is performing the survey as this form was historically only used by SAs. Consequently, the form directions do not refer to AOs. Since this is a public document that is frequently used by consumers, advocacy groups, and the public as a source of information about quality of care and facility compliance, CMS must make updates to the form to include AO information so it is clear who performed the survey. CMS is in the process of seeking the Office of Management and Budget (OMB) approval of this revised form for information collection, in accordance with provisions of the Paperwork Reduction Act (PRA). For further discussion on PRA implications and timeline, see the collection of information requirements in section X. of this proposed rule.

We seek public comment on how AOs can customize their proprietary systems to incorporate a version of the Form

[91] CMS–2567 available at: *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2567.pdf.*

[92] iQIES is available at: *https://iqies.cms.gov/.*

CMS–2567 and then submit it to CMS via electronic data exchange.

c. Release and Use of Accreditation Surveys (§ 488.7)

We propose to add a new § 488.7(c), which would require the posting of the Form CMS–2567 in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates. Prior to the CAA 2021, CMS did not have the authority to publish AO surveys for deemed hospice programs except to the extent that the AO survey and survey information are related to an enforcement action taken by CMS against the provider. However, CMS may post State agency complaint or validation survey results of deemed hospice providers; CMS utilizes the Quality, Oversight, and Certification Reports (QCOR) [93] public website for this purpose.

As mentioned in section VII.B.1.b. of this proposed rule, CMS recognizes there are challenges related to the system implications for use of the Form CMS–2567 by the AOs. However, as directed by Congress, we are removing the prohibition that previously allowed AO hospice program survey reports to be considered confidential and proprietary. We are proposing to require that AOs release deficiency reports for hospice program surveys conducted under their respective deeming authority to increase transparency among the hospice beneficiary community.

CMS will need to address various system integrations and updates to integrate AO survey results on the Form CMS–2567 as mentioned in section VII.B.2.b. of this proposed rule. Furthermore, CMS recognizes there are limitations and additional data system changes to consider for survey results from the Form CMS–2567 to be displayed in a meaningful and useful format.

We seek public comments as to how data elements from the Form CMS–2567 may be utilized and displayed, and other recommendations of relevant provider information, to assist the public in obtaining a more comprehensive understanding of a hospice program's overall performance. CAA 2021 requires that CMS publish survey information from the Form CMS–2567 in a way that is readily understandable and useable by the public in a meaningful way. We anticipate the need for us to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices' performance. We recognize that the implications of releasing national survey data will require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.

d. Providers or Suppliers, Other Than SNFs, NFs, HHAs, and Hospice Programs With Deficiencies (§ 488.28)

Currently, the regulation at § 488.28 states that if a provider or supplier is deficient in one or more of the standards set out in such provider's or supplier's CoPs, it must submit an acceptable plan of correction (POC) for achieving compliance. An acceptable POC must be received within a reasonable time acceptable to CMS to continue Medicare participation. If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards in the CoPs, it is granted a ''reasonable time'' to achieve compliance. The amount of time depends upon the nature of the deficiency and the SA's discretionary determination as to whether the facility can provide adequate and safe care. Ordinarily, a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies. However, the SA may recommend additional time be granted based on individual situations if it is not reasonable to expect compliance within 60 days. The regulation exempts SNFs, NFs, and HHAs from this requirement; instead, similar provisions are set out in the regulations relating to those specific provider-types.

Section 1822(c) of the Act authorizes the Secretary to take actions to ensure the removal and correction of condition-level deficiencies in a hospice program through an enforcement remedy or termination or both. The enforcement remedy requirements for hospice programs are outlined in the proposed new subpart N. Regardless of which remedy is applied, a non-compliant hospice program must still submit a POC for approval by the SA or CMS. The POC is a plan developed by the hospice program and approved by CMS that is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and the hospice program specifies the date by which those deficiencies will be corrected. We propose revising the heading for § 488.28 to indicate that hospice programs with deficiencies would also be exempt from the enforcement requirements set out in that section of our rules.

3. Proposed New Subpart M—Survey and Certification of Hospice Programs

a. Basis and Scope (§ 488.1100)

The proposed regulation at § 488.1100 would specify the statutory authority and general scope of the hospice program. In general, this proposed rule is based on the rulemaking authority in section 1822 of the Act as well as specific statutory provisions identified in the preamble where appropriate.

b. Definitions (§ 488.1105)

We propose to add definitions at § 488.1105 for survey and enforcement terms for hospice programs. The definitions proposed for hospice programs include the following:

- *Abbreviated standard survey* would mean a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or CoPs. An abbreviated standard survey may be based on complaints received or other indicators of specific concern. Examples of other indicators include media reports or findings of government oversight activities, such as OIG investigations.
- *Complaint survey* would mean a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.
- *Condition-level deficiency* would mean noncompliance as described in § 488.24 of this part.
- *Deficiency* would mean a violation of the Act and regulations contained in 42 CFR part 418, subparts C and D, is determined as part of a survey, and can be either standard or condition-level.
- *Noncompliance* would mean any deficiency found at the condition-level or standard-level.
- *Standard-level deficiency* would mean noncompliance with one or more of the standards that make up each condition of participation for hospice programs.
- *Standard survey* would mean a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards and/or CoPs to determine the quality of care and services furnished by a hospice program.
- *Substantial compliance* would mean compliance with all condition-level requirements, as determined by CMS or the State.

c. Hospice Program Surveys and Hospice Program Hotline (§ 488.1110)

At proposed § 488.1110(a), a standard survey would have to be conducted not

[93] Quality, Certification and Oversight Reports (QCOR).

later than 36 months after the date of the previous standard survey, as specified in section 1822(a)(1) of the Act. A survey could be conducted more frequently than 36 months to assure that the delivery of quality hospice services complies with the CoPs and confirm that the hospice program corrected deficiencies that were previously cited. At proposed § 488.1110(b)(1), a standard or abbreviated standard survey would have to be conducted when complaint allegations against the hospice program were reported to CMS, the State, or local agency. Additionally, we recognize that for AOs with hospice deeming programs, the proposed 36-month surveys would mirror the requirements for AOs to describe the frequency of surveys as part of the AO application process at existing § 488.5(a)(4)(i). That provision requires AOs to agree to survey and re-survey every accredited provider or supplier, through unannounced surveys, no later than 36 months after the prior accreditation effective date, or shorter if there is a statutorily mandated survey interval of fewer than 36 months.

Prior to the amendments made by CAA 2021, section 1864(a) of the Act required that agreements between the Secretary and the State, under which SAs carry out the Medicare certification process, shall provide for the appropriate State or local agency to establish and maintain a toll-free hotline for HHAs. The CAA 2021 amended this requirement to include hospice programs. The provision now requires that a hotline must be maintained: (1) To collect, maintain, and continually update information on HHAs and hospice programs located in the State or locality that are certified to participate in the program established under this title; and (2) to receive complaints (and answer questions) with respect to HHAs and hospice programs in the State or locality. Section 1864(a) of the Act also provides that such agreements shall provide for the State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1865 of the Act, and consumer medical records (but only with the consent of the consumer or his or her legal representative). We propose to build on these same requirements for hospice programs consistent with the amendments made to section 1864(a) of the Act by CAA 2021.

Therefore, at § 488.1110(b)(2) we propose that the State or local agency is responsible for establishing and maintaining a toll-free hotline to receive complaints (and answer questions) with respect to hospice programs in the State or locality and for maintaining a unit to investigate such complaints. The requirement for the hotline will be described in the annual CMS Quality, Safety and Oversight Group's Mission and Priority Document (MPD) that serves as the scope of work which State Agencies are bound contractually via section 1864 of the Act (42 U.S.C. 1395aa).

As we plan for the implementation of the hospice toll-free hotline to streamline and enhance the complaint process for hospice program beneficiaries, we seek public comment on current experiences with the HHA toll-free hotline as required by section 1864(a) of the Act. This information will inform CMS of future enhancements to the toll-free hotline. Specifically, what data elements and processes should be included to assure confidentiality and immediate communication with relevant SAs in order to permit them to respond promptly.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

Section 1822(a)(4)(C) of the Act requires the Secretary to provide training for State and Federal surveyors, and any surveyor employed by an AO, including a training and testing program approved by the Secretary, no later than October 1, 2021. Further, no surveyor can conduct hospice program surveys until they complete training and testing. Currently, AOs are required by § 488.5(a)(8) to provide training to their surveyors. As the AO requirements outlined in § 488.5 also allow for standards and processes that exceed those of CMS, the AO's training may differ from what CMS provides to SA surveyors, thereby creating a potential disparity in overall survey performance. At § 488.1115, we propose that all SA and AO hospice program surveyors would be required to take CMS-provided surveyor basic training currently available, and additional training as specified by CMS. As part of the AO application and reapplication process under § 488.5(a)(8), the AO is required to submit a description of the content and frequency of the organization's in-service training it provides to survey personnel. Under proposed § 488.1115, AO surveyors would be required to complete the online CMS hospice program basic training. CMS proposes that until the rule is finalized, that it accept the current AO training, that was previously reviewed and approved by CMS during the AO application process. State agency surveyors should already be in compliance with this requirement.

AOs already have voluntary access to our Quality, Safety & Education Portal (QSEP), which contains the CMS training. Currently, the trainings are available free of charge through the QSEP website at *https://qsep.cms.gov,* to providers and all entities conducting surveys, including AOs, and the public at large. QSEP training is accessible on an individual, self-paced basis.

The basic training online courses provide surveyors with the key knowledge and skills needed to survey the respective provider or supplier type for compliance with the Medicare conditions and assure an adequately trained, effective surveyor workforce. The online courses also help develop and refine surveying skills, promote critical thinking skills, and enhance surveyors' overall ability to conduct and document surveys. Users may access the online courses at any time. This allows surveyors to refresh knowledge regarding Medicare conditions and processes whenever necessary. The number of learners trained in online courses has steadily increased since the courses' inception.

We are updating the hospice program basic training and including enhanced guidance for surveyors. The updated training will emphasize assessment of quality of care. Specifically, we would emphasize four ''core'' hospice program CoPs in revisions to the CMS State Operations Manual (SOM) (Pub. 100–07). The four core CoPs (identified in the preamble of the final rule, Medicare and Medicaid Programs; Hospice Conditions of Participation (73 FR 32088, June 5, 2008)) are § 418.52 Condition of Participation: Patient's rights; § 418.54 Condition of Participation: Initial and comprehensive assessment of the patient; § 418.56 Condition of Participation: Interdisciplinary group, care planning and coordination of care; and, § 418.58 Condition of Participation: Quality assessment and performance improvement. The revised training, which we expect to be implemented soon, emphasizes the requirements for establishing individualized written plans of care, which are integral to the delivery of high quality care, and regularly updating these plans with the full involvement of the interdisciplinary team, patients, and their families. Despite the emphasis placed on these core CoPs, hospice programs must comply with all CoPs to achieve successful certification.

We invite commenters to review the trainings by signing up for a free

account on the homepage of the CMS website, or by choosing the ''Public Access'' button on the upper right-hand corner of the website homepage. We seek comments on the requirement for continued SA and AO surveyor training as CMS releases additional basic course updates.

In addition to training requirements for surveyors, we propose to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with section 1822(a)(4)(B) of the Act. While the statute specifically addresses SA surveyors, CMS takes prohibiting violations of public trust for those representing the Medicare program very seriously and therefore we are proposing to include hospice AO surveyors under this proposed requirement as well.

In 2012, as part of an effort to mitigate conflicts of interest in the HHA survey process, CMS established requirements at § 488.735(b) to outline circumstances that disqualify a surveyor from performing HHA surveys. For example, if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the HHA undergoing the survey, they would be disqualified for a conflict of interest.

Chapter 4, Section 4008 of the SOM states, ''conflicts of interest may arise within the Medicare/Medicaid certification program when public employees utilize their position for private gain or to secure unfair advantages for outside associates. The gain involved may or may not be monetary. Abuses of privileged information, abuses of influence, and other abuses of trust are included, regardless of whether a monetary advantage is gained or sought.'' [94]

Individual health care professionals, such as physicians or nurses, commonly have concurrent employment relationships with more than one health care setting. Many health care professionals, such as physicians, physician assistants, and nurse practitioners have multi-setting practices or are employed at more than one health care facility. For example, a registered nurse (RN) may work on staff at a hospital but also work at other hospitals through a medical staffing agency. In addition, as employees of a health care facility, these health care professionals could gain a financial interest in the health care facility through means such as being a contributor to the construction costs of a new wing of the facility or buying stock in the facility or its parent corporation. Management employees could be awarded stock or stock options for the facility or its parent corporation as part of their compensation and benefits package.

SAs and AOs often hire surveyors that are also employed at one or more outside health care settings because the professional associations, expertise, knowledge, and skills held by these health care practitioners make them an asset as a surveyor. Longstanding CMS policy noted in section 4008 of the SOM describes examples of scenarios that would be conflicts of interest for SA surveyors of any provider or supplier type, including surveyors who have an outside relationship with a facility that is surveyed by the SA. However, the SOM generally applies only to SA surveyors, not AO surveyors. Therefore, we propose to codify these long-standing policies for both SA and AO surveyors to ensure there is no conflict of interest between the organization and the surveyor.

We propose that a surveyor would be prohibited from surveying a hospice program if the surveyor currently serves, or within the previous 2 years has served, on the staff of or as a consultant to the hospice program undergoing the survey. Specifically, the surveyor could not have been a direct employee, employment agency staff at the hospice program, or an officer, consultant, or agent for the surveyed hospice program regarding compliance with the CoPs. A surveyor would be prohibited from surveying a hospice program if he or she has a financial interest or an ownership interest in that hospice. The surveyor would also be disqualified if he or she has an immediate family member who has a financial interest or ownership interest with the hospice program to be surveyed or has an immediate family member who is a patient of the hospice program to be surveyed.

In regards to the definition of ''immediate family member'' in the previous statement, we will utilize the definition of ''immediate family member'' located at § 411.351, which was also used for the development of similar HHA regulations (see 77 FR 67140). This definition includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

e. Survey Teams (§ 488.1120)

The CAA 2021, adding section 1822(a)(4)(A) of the Act, calls for the use of multidisciplinary survey teams when the survey team comprises more than one surveyor, with at least one person being a RN. Currently, the SOM, Appendix M—Guidance to Surveyors requires that each hospice program survey team include at least one RN, and, if the team is more than one surveyor, the additional surveyors should include other disciplines with the expertise to assess hospice program compliance with the conditions of participation. We propose at § 488.1120 under a new subpart M to require that all survey entities—SA or AOs—include diverse professional backgrounds among their surveyors to reflect the professional disciplines responsible for providing care to persons who have elected hospice care. Such multidisciplinary teams should include professions included in hospice core services at 42 CFR 418.64, and may include physicians, nurses, medical social workers, pastoral or other counselors—bereavement, nutritional, and spiritual. To fulfill CAA 2021 requirements, SAs and AOs might need time to reconstruct their workforce to accommodate the new requirements for hospice program surveys to utilize multidisciplinary teams.—We recognize that SAs and AOs may incur additional costs, given the varying, and potentially higher rates of average pay for some disciplines. Surveying entities may need up to a year to hire and train surveyors from the needed disciplines, depending on the timing of the attrition of current staff and workforce availability of the appropriately experienced professionals. In addition, as we proceed with implementation of this provision, CMS seeks to better understand the current professional makeup of survey entities' workforces. In order to track compliance with this provision, we propose to establish a baseline knowledge by asking survey entities to tell us: (1) The extent to which their surveys are conducted by one professional, who by regulation must be a registered nurse; (2) the professional makeup of their current workforce; and (3) estimate a timeframe in which they could effectuate multidisciplinary teams if not already in place. We would provide additional guidance with instruction for the survey entities regarding the submission of this information to CMS.

Our rules at § 418.56 require that hospice programs use interdisciplinary teams or groups to determine a holistic plan of care for the hospice program

[94] CMS State Operations Manual, Chapter 4 Medicare State Operations Manual (*cms.gov*) (*internet Only Manual, Pub. 100–07*)

patient and family. The interdisciplinary group or IDG, must include, but not be limited to a physician, a registered nurse, a medical social worker, and pastoral or other counselor. Therefore, we propose that when the survey team comprises more than one surveyor, the additional slots would be filled by professionals from among these disciplines, and we are seeking comments on this approach. Similarly, section 1819(g)(2)(E) of the Act and 42 CFR 488.314 require that long-term care facility surveys be conducted by a multidisciplinary team of professionals, at least one of whom must be a RN.

Our certification guidance in Chapter 2 of the SOM provides details as to how the survey agency might select the appropriate disciplines for a survey team. SOM, Chapter 2 states that various professional disciplines should represent the expertise needed to determine compliance with the CoPs, standards, or requirements for that provider/supplier group. In establishing multidisciplinary teams under new section 1822(a)(4)(A) of the Act, we would consider, as a model, our current CMS guidance for long-term care facilities, which uses specialty surveyors with expertise not typically included in a survey team (for example, a pharmacist, physician, or registered dietitian), who may not be needed for the entire survey, but must be onsite at some time during the survey.

f. Consistency of Survey Results (§ 488.1125)

New section 1822(a)(3) of the Act requires that each State and the Secretary implement programs to measure and reduce inconsistency in the application of hospice program survey results among surveyors. In addition to ensuring consistency of hospice survey results across SAs, we believe that this also applies to reducing discrepancies between SA and AO surveys of hospice providers. Survey consistency has been a longstanding concern for CMS at multiple levels—interstate and intrastate, as well as Federal to state. While there are multiple strategies currently in place, as described in this section, to directly address the matters presented in the CAA 2021, we propose at § 488.1125 to enhance the requirements of the State Performance Standards System (SPSS) to direct States to implement processes to measure the degree or extent to which surveyors' findings and determinations are aligned with federal regulatory compliance and with an SA supervisor's determinations. Given the variation among State agencies with respect to the number of surveyors deployed for a particular survey, or the distribution of surveyor professional backgrounds, CMS expects to promulgate objective measures of survey accuracy, and seeks public opinion on what measures would be feasible for States. We desire measures that are both specific and utilize currently collected data, if possible. Accuracy could include whether a survey finding aligns with the selected regulatory deficiency, as well as failing to cite such findings. When applied to survey findings, the measures should allow CMS to determine the need for corrective action or education for individual surveyors or for a group of surveyors. If systemic issues are found, CMS is prepared to enhance its training to address systemic issues found as a result of interstate analysis.

CMS monitors the consistency of SA surveys through a review of an SA's Form CMS–2567s (the Statement of Deficiencies and Plan of Correction), which is conducted by its assigned CMS Survey Operations Group (SOG) Location, and consistency among AOs through validations surveys conducted by SAs. The SAs perform validation surveys on a sample of providers and suppliers (such as hospitals, CAHs, ASCs, Hospice Programs, and HHAs) accredited by the AOs. Validation surveys report disparate findings as the percentage of validation surveys that have conditions identified by the SA but missed by the AO survey team. This percentage is referred to as the ''disparity rate'' and is tracked by CMS as an indication of the quality of the surveys performed by the AO. This is reported annually in a report to Congress (*QSO–19–17–AO/CLIA*). The most recent report can be found at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-and-Regions-Items/AdminInfo-20-02-ALL.*

Using the disparity rate approach used with AOs, where surveys are reviewed for condition-level deficiencies the AO fails to identify, we propose to analyze trends in the disparity rate among States, as well as among AOs. State surveys results would be reviewed to identify findings that were potentially worthy of condition-level citation but were not cited.

We believe that the disparate deficiency citations between AO surveyors and SA surveyors may, in part, be attributed to differences in surveyor training and education. This variation may be due to inconsistencies in AO training with the CMS-provided SA basic surveyor training. We believe that uniform surveyor training would increase the consistency between the results of the surveys performed by SAs and AOs, and have a positive impact on the high disparity rates. We also want to align our processes more closely to those CMS has found effective for other provider types. For instance, what we propose now, for hospice, is similar to what is done with nursing homes, where validation surveys are described at section 1819(g)(3)(A) of the Act as ''. . . a representative sample of skilled nursing facilities in each State, within 2 months of the date of surveys conducted under paragraph (2) by the State, in a sufficient number to allow inferences about the adequacies of each State's surveys . . . (B) . . . each year concerning at least 5 percent of the number of skilled nursing facilities surveyed by the State in the year, but in no case less than 5 skilled nursing facilities. . . .'' Even though AOs are not currently included in the CMS SPSS, we expect that a similar methodology would be applied to all hospice surveying entities, including AOs with an approved hospice program. Just as CMS monitors disparate results across States in their adherence to Federal processes for determining deficiencies, investigating, and reporting complaints, it requires States to monitor the quality of its surveyors' survey activity and actions. Performance measures are applied to all surveying entities to assess consistency. If CMS finds that surveying entities—SAs and AOs—do not meet the performance standards, they must develop and implement a corrective action plan.

The SPSS, established annually, provides for oversight of SA performance when conducting surveys to ensure that Medicare and Medicaid certified providers and suppliers are compliant with Federal CoPs, to improve and protect the health and safety of Americans. This oversight allows CMS to determine that surveyors are thorough, accurate, and consistent when they determine if a hospice program provider is complying with the Medicare CoPs. Survey findings with respect to a hospice program can include: (1) Standard level deficiency—where the hospice program is not complying fully with CoPs, which need corrective action; (2) condition-level deficiencies—which require remediation and could lead to termination of the hospice program; or, (3) immediate jeopardy (IJ) level—where beneficiaries are present in situations where significant harm could occur and which need to be addressed without delay. SA supervisors are responsible to

ensure that surveyors 'findings (from observations, interviews, and document reviews) are consistent with their determination of IJ, and standard- or condition-level deficiency where a hospice program is not compliant with a condition of participation.

To reduce inconsistencies in survey results among surveyors, CMS proposes to require agencies that review other entities' survey findings for missed condition-level deficiency citations (disparities) (SAs for AOs, and CMS SOG locations for SAs), to notify each survey entity of its disparity rate annually, and to require a formal corrective plan as part of the survey entity's (SA or AO) Quality Assurance program. A disparity rate above 10 percent in 2 consecutive cycles would trigger remedial activity such as implementing corrective action through education, mentoring, or other processes to align surveyors' actions, and determinations of deficiencies with regulatory requirements.

g. Special Focus Program (SFP) (§ 488.1130)

Section 1822(b) of the Act requires the Secretary to conduct a Special Focus Program for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements of the Act. We propose at § 488.1130 to develop a hospice Special Focus Program (SFP) to address issues that place hospice beneficiaries at risk for poor quality of care through increased oversight, and/or technical assistance. We propose that specific criteria would be used to determine whether a hospice program participates in the SFP. The proposed criteria are as follows: a history of condition-level deficiencies on two consecutive standard surveys, two consecutive substantiated complaint surveys, or two or more condition-level deficiencies on a single validation survey (the validation survey with condition-level deficiencies would be in addition to a previous recertification or complaint survey with condition-level deficiencies). A subset of hospice programs that meet the proposed criteria would be selected to be in the SFP, and those hospice programs would be surveyed every 6 months, which may result in additional enforcement remedies and/or termination. CMS uses a similar program with long-term care facilities and has outlined the following protocol for a hospice SFP:

- The SA and CMS SOG location would receive a list from CMS of all hospice programs that meet the established criteria at § 488.1130(b) for placement in the SFP (Candidate List). The SA would work with the CMS SOG location to select hospice programs from the list provided by CMS that would be selected for the SFP based on State priorities. In the event that no hospice programs in a State meet the established criteria, then the State SA would not have a hospice program in the SFP at that time.
- While a hospice program is in the SFP, the SA would survey the facility at least once every 6 months, as required by the CAA 2021, and may include progressively stronger enforcement actions in the event of a hospice program's continued failure to meet the requirements for participation with the Medicare and Medicaid programs.
- Once an SFP hospice program has completed 2 consecutive 6-month SFP surveys with no condition-level deficiencies cited, the facility would graduate from the SFP. If the hospice program did not meet the requirements to graduate, it would be placed on a termination track.

We seek public comment regarding the SFP, specifically the following issues:

- Should CMS utilize a similar criteria/process/frame work for the SFP as outlined in the current Long-Term Care Program. What if any differences should CMS considered to enhance the overall impact of the hospice SFP.
- Additional selection criteria that CMS should consider for the identification and participation in the SFP. This may include use of current or future data elements that could be incorporated into a more comprehensive algorithm.
- Utilization of a Technical Expert Panel (TEP) to enhance the SFP in terms of selection, enforcement and technical assistance criteria while in the program. Furthermore, a TEP may assist CMS by assisting in identifying contextual data and relevant information to assist the public in obtaining a more comprehensive understanding of the Form CMS–2567 survey data and the overall performance of a hospice provider, in addition to what data to include, how to make this information useful and meaningful on a CMS website.

4. Proposed New Subpart N—Enforcement Remedies for Hospice Programs With Deficiencies

a. Statutory Basis (§ 488.1200)

We propose to set out the statutory basis for the proposed new subpart at § 488.1200, which is new sections 1822(c)(1) through 1822(c)(5) of the Act. The requirements under this new subpart would expand the Secretary's options to impose additional enforcement remedies for hospice programs failing to meet Federal requirements. These additional enforcement remedies may be used to encourage poor-performing hospice programs to come into substantial compliance with CMS requirements before CMS is forced to terminate the hospice program's provider agreement. This process is currently afforded to HHAs at § 488.745.

Prior to the enactment of section 1822(c)(5)(A) of the Act, the only enforcement action available to CMS to address hospice programs that are determined to be out of compliance with Federal requirements was the termination of their Medicare provider agreement. In accordance with section 1866(b)(2) of the Act and § 489.53(a)(3), CMS may terminate a hospice program provider agreement if that hospice program is not in substantial compliance with the Medicare requirements (that is, the failure to meet one or more CoPs is considered to be a lack of substantial compliance).

b. Definitions (§ 488.1205)

We propose to add § 488.1205 to define the terms ''directed plan of correction,'' ''immediate jeopardy,'' ''new admission,'' ''per instance,'' ''plan of correction,'' ''repeat deficiency,'' and ''temporary management.'' Although section 1891 of the Act uses the term ''intermediate sanctions,'' with respect to HHA enforcement, and other rules use ''alternative sanctions,'' we propose to use ''remedies'' or ''enforcement remedies,'' which we consider to have the same meaning and are closer to the language in section 1822 of the Act.

c. General Provisions (§ 488.1210)

We propose at § 488.1210 general rules pertaining to enforcement actions against a hospice program that is not in substantial compliance with the CoPs. Under section 1822(c)(1) of the Act, if CMS determines that a hospice program is not in compliance with the Medicare hospice programs CoPs and the deficiencies involved may immediately jeopardize the health and safety of the individual(s) to whom the hospice program furnishes items and services, then we may terminate the hospice program's provider agreement, impose the one or more enforcement remedies described in section 1822(c)(5)(B) of the Act, or both. Our decision to impose one or more remedies, including termination, will be based on the degree of noncompliance with the hospice program Federal requirements. With the proposed provisions, CMS would be able to impose one or more remedies for

each discrete condition-level deficiency constituting noncompliance.

It is also important to note that hospice programs can acquire initial certification for participation in Medicare via an SA survey or via accreditation by a CMS-approved AO. Accreditation by a CMS-approved AO is voluntary and not necessary to participate in the Medicare program. If an AO finds deficiencies during an accreditation survey, it communicates any condition-level findings to the applicable CMS SOG location. Based on the survey findings, CMS makes any determinations regarding the imposition of Federal enforcement remedies. An AO cannot recommend or implement enforcement remedies. In accordance with SOM Chapter 2, section 2005B, CMS may temporarily remove deemed status of an accredited hospice program due to condition-level findings found by the SA or Federal survey team during a complaint or validation survey. If the deficiencies remain uncorrected, oversight of that hospice program is transferred to CMS, through the SA, until the hospice program either demonstrates substantial compliance or CMS terminates its Medicare participation. In such a case where ''deemed status'' is removed, CMS will follow the usual procedures for oversight, as indicated in sections 3254 and 5100 of the *SOM.* Once an enforcement remedy is imposed on a formerly accredited hospice program and deemed status is removed, oversight and enforcement of that hospice program will be performed by the SA until the hospice program achieves compliance and the condition(s) causing the noncompliance are removed or until the hospice program is terminated from the Medicare program.

At proposed § 488.1210(e), a hospice program would be required to submit an acceptable POC to the SA or CMS within 10 calendar days from receipt of the statement of deficiencies. This plan is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and the date by which those deficiencies will be corrected. CMS would determine if the POC was acceptable based on the information presented.

At proposed § 488.1210(e), we propose the notification requirements for enforcement remedies for hospice programs that will be issued by CMS. CMS will provide a notice of intent to the hospice program that would include the intent to impose a remedy, the statutory basis for the remedy, the nature of the noncompliance, the intent to impose a payment suspension and which payments would be suspended (if applicable), the intent to propose a CMP and the amount being imposed (if applicable), the proposed effective date of the sanction, and appeal rights.

We propose that for all remedies imposed, except for CMPs, when there is IJ the notice period is at least 2 calendar days before the effective date of the enforcement action and when there is no IJ, that the notice period is at least 15 calendar days before the effective date of the enforcement action. As discussed later in this section, we propose to codify these proposals at §§ 488.1225(b) and 488.1230(b), respectively.

With respect to CMPs, we propose that once the administrative determination to impose the CMP is final, CMS would send a final notice to the hospice program with the amount of the penalty assessed, the total number of days of noncompliance (for CMPs imposed per day), the total amount due, the due date of the penalty, and the rate of interest to be charged on unpaid balances. We propose to codify these proposals at § 488.1245(e).

We propose that the hospice program could appeal the determination of noncompliance leading to the imposition of a remedy under the provisions of 42 CFR part 498. A pending hearing would not delay the effective date of the remedy against the hospice program and remedies will be in effect regardless of any pending appeals proceedings. Civil money penalties would accrue during the pendency of an appeal, but would not be collected until the administrative determination is final, as we note in proposed § 488.1245(f).

d. Factors To Be Considered in Selecting Remedies (§ 488.1215)

Section 1822(c) of the Act provides that if a hospice program is found to be out of compliance with the requirements specified in section 1861(dd) of the Act, CMS may impose one or more specified enforcement remedies. In this proposed rule, we have proposed to establish requirements for enforcement remedies that may be imposed when hospice programs are out of compliance with Federal requirements. At CMS' discretion, these enforcement remedies can be imposed instead of, or in addition to, termination of the hospice program's participation in the Medicare program, for a period not to exceed 6 months. The choice of any enforcement remedy or termination would reflect the impact on patient care and the seriousness of the hospice program's patterns of noncompliance and would be based on the factors proposed in § 488.1215. CMS may impose termination of the provider agreement (that is, begin termination proceedings that would become effective at a future date, but no later than 6 months from the determination of noncompliance), and impose one or more remedies for hospice programs with the most egregious deficiencies, on a hospice program that was unwilling or unable to achieve compliance within the maximum timeframe of 6 months, whether or not the violations constituted an IJ situation. We propose at § 488.1215, consistent with section 1822(5)(B)(i) of the Act, to establish procedures for selecting the appropriate enforcement remedy, including the amount of any CMP and the severity of each remedy, which have been designed to minimize the time between the identification of deficiencies and the final imposition of remedies, as required under section 1822(c)(5)(A)(ii) of the Act. To determine which remedy or remedies to apply, CMS proposes to consider the following factors that are consistent with the factors for HHA alternative sanctions:

- The extent to which the deficiencies pose IJ to patient health and safety.
- The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.
- The presence of repeat deficiencies (defined as condition-level), the hospice program's compliance history in general, and specifically concerning the cited deficiencies, and any history of repeat deficiencies at any of the hospice program's additional locations.
- The extent to which the deficiencies are directly related to a failure to provide quality patient care.
- The extent to which the hospice program is part of a larger organization with documented performance problems.
- Whether the deficiencies indicate a system-wide failure of providing quality care.

e. Available Remedies (§ 488.1220)

Section 1822(c)(5)(A)(ii) of the Act provides that CMS ''shall develop and implement specific procedures for the conditions under which each of the remedies developed under clause (i) is to be applied, including the amount of any fines and the severity of each of these remedies.'' Section 1822(c)(5)(B) of the Act explicitly provides for the following enforcement remedies to be included in the range of remedies: (1) CMPs in an amount not to exceed $10,000 for each day of noncompliance by a hospice program with the requirements specified in section

1861(dd) of the Act; (2) suspension of all or part of the payments to which a hospice program would otherwise be entitled under this title for items and services furnished by a hospice program, on or after the date on which the Secretary determines that remedies should be imposed; and (3) appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made to bring the program into compliance with all such requirements. In addition to those specified in the statute, we propose to add a directed POC and directed in-service training as additional enforcement remedies at § 488.1220.

f. Action When Deficiencies Pose Immediate Jeopardy (§ 488.1225) and Termination (§ 489.53)

For situations involving IJ, if CMS determines based on a standard survey or otherwise that a hospice program's deficiencies involve IJ to the health and safety of the individuals to whom the program furnishes items and services, it shall take immediate action to ensure the removal of the IJ and to correct the deficiencies or terminate the certification of the program. We are proposing at § 488.1225(a) to implement the statutory requirement of 1822(c)(1) of the Act by specifying that if the IJ situation is not addressed and resolved within 23 days from the last day of the survey because the hospice program is unable or unwilling to correct the deficiencies, CMS will terminate the hospice program's provider agreement. In addition, CMS could impose one or more enforcement remedies including a CMP, temporary management, and/or suspension of all or part of Medicare payments before the effective date of termination.

We propose § 488.1225(b), that for a deficiency or deficiencies that pose IJ, CMS would provide the hospice program with at least 2 days advance notice of any proposed remedies, except CMPs (discussed at proposed § 488.1245). The requirements for a notice of intent are set forth at proposed § 488.1210(e). Under our existing survey process, providers are informed of any IJ findings upon discovery of the IJ situation during the survey or as part of the exit conference at the end of the survey. This would give a hospice program time to remove the IJ and correct the deficiencies that gave rise to the IJ finding. To assure a hospice program achieves prompt compliance, we expect that CMS will give hospice programs written notice of an impending enforcement actions against them as quickly as possible following the completion of a survey of any kind.

For terminations, CMS will give notice of the termination within 2 days before the effective date of the termination, to hospice programs consistent with the requirement for HHAs. We also propose to amend § 489.53(a)(17) to indicate that we will terminate a hospice program's (as well as an HHA's) provider agreement if the hospice program failed to correct a deficiency or deficiencies within the required time frame.

Finally, at proposed § 488.1225(c), we propose to require a hospice program whose provider agreement is terminated to appropriately and safely transfer its patients to another local hospice program within 30 days of termination, unless a patient or caregiver chooses to remain with the hospice program as a self-pay or with another form of insurance (for example, private insurance). In addition, the hospice program would be responsible for providing information, assistance, and any arrangements necessary for the safe and orderly transfer of its patients.

g. Action When Deficiencies Are at the Condition-Level But Do Not Pose Immediate Jeopardy (§ 488.1230)

In section 1822(c)(2) of the Act, if the Secretary determines based on a survey or otherwise that a hospice program is no longer in compliance with the requirements specified in section 1861(dd) of the Act and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose remedies developed under section 1822(c)(5)(A) of the Act, in lieu of terminating hospice program's participation in the Medicare program. If, after such a period of remedies, the program is still not in compliance with all requirements, the Secretary shall terminate the hospice program's participation in the Medicare program.

In this proposed rule, enforcement remedies, such as those proposed in § 488.1220, would be imposed before the termination becomes effective, but cannot continue for a period that exceeded 6 months. In addition, to protect the health and safety of individuals receiving services from the hospice program, enforcement remedies would continue in effect until the hospice program achieves compliance or has its Medicare participation terminated, whichever occurs earlier. For example, the suspension of payment remedy will end when the hospice program corrects all condition-level deficiencies or is terminated from the Medicare program.

We propose at § 488.1230, that for a deficiency or deficiencies that do not pose IJ, CMS will provide the hospice program at least 15 days advance notice of any proposed remedies, except for CMPs (discussed at proposed § 488.1245). Such remedies would remain in effect until the effective date of an impending termination (at 6 months) or until the hospice program achieves compliance with CoPs, whichever is earlier. This 15-day period is consistent with the general rule for providers and suppliers in § 489.53(d)(1).

h. Temporary Management (§ 488.1235)

Section 1822(c)(5)(B)(iii) of the Act specifies the use of appointment of temporary management, as an enforcement remedy, to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made in order to bring the program into compliance with all such requirements. As we propose at § 488.1205, ''temporary management'' means the temporary appointment by CMS or a CMS authorized agent, of a substitute manager or administrator, who would be under the direction of the hospice program's governing body and who would have authority to hire, terminate or reassign staff, obligate hospice program funds, alter hospice program procedures, and manage the hospice program to correct deficiencies identified in the hospice program's operation. The substitute manager or administrator would be appointed based on qualifications described in § 418.100 and § 418.114 and would be under the direction of the hospice program's governing body.

We propose at § 488.1235 to set out the circumstances under which we would utilize our authority under section 1822(c)(5)(C)(iii) of the Act to place a hospice program under temporary management. We propose to specify the duration and effect of this enforcement remedy, and the payment procedures for temporary managers' salaries and other additional costs. CMS would provide the hospice program with written notice of our intent to impose a temporary management remedy in accordance with proposed § 488.1210(e).

At § 488.1235(a), we propose that temporary management would be imposed when a hospice program is determined to have condition-level deficiencies and that the deficiencies or

the management limitations of the hospice program are likely to impair the hospice program's ability to correct the deficiencies and return the hospice program to compliance with all of the CoPs within the required timeframe. We propose at § 488.1235(c) to impose temporary management to bring a hospice program into compliance with program requirements within 6 months of the date of the survey identifying noncompliance.

We propose at § 488.1235(b) if the hospice program refuses to relinquish authority and control to the temporary manager, CMS will terminate the hospice program's provider agreement. If a temporary manager was appointed, but the hospice program failed to correct the condition-level deficiencies within 6 months from the last day of the survey, the hospice program's Medicare participation would be terminated. Additionally, if the hospice program resumes management control without CMS's approval, we would impose termination and could impose additional enforcement remedies. The appointment of a temporary manager would not relieve the hospice program of its responsibility to achieve and maintain compliance with the participation requirements. We propose at § 488.1235 that temporary management would end when—

- We determine that the hospice program has achieved substantial compliance and has the management capability to remain in compliance;
- The hospice program provider agreement is terminated; or
- The hospice program resumes management control without CMS approval.
- Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

At § 488.1235, we propose that temporary management would be required to be provided at the hospice program's expense. Before the temporary manager was installed, the hospice program would have to agree to pay his/her salary directly for the duration of the appointment. We believe that the responsibility for the hospice program to pay the expenses of the temporary manager is an inherent management responsibility of the hospice agency for which Medicare regularly reimburses the hospice program and through such temporary outside management might be necessary in some cases to bring the hospice program back into compliance with the CoPs. We are proposing that the salary for the temporary manager would not be less than the amount equivalent to the prevailing salary paid by providers in the geographic area for positions of this type, based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates. In addition, the hospice program would have to pay for any additional costs that the hospice program may have incurred if such person had been in an employment relationship, and any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State. CMS would consider a hospice program's failure to pay the salary of the temporary manager to be a failure to relinquish authority and control to temporary management.

i. Suspension of Payment for All or Part of the Payments (§ 488.1240)

We propose in § 488.1240 provisions describing when and how we would apply a suspension of payment of all or part of the payments for items and services furnished by a hospice program on or after the date on which the Secretary determines that remedies should be imposed under § 488.1225 or § 488.1230. If a hospice program has a condition-level deficiency or deficiencies (regardless of whether or not an IJ exists), we may suspend payments for all or part of the payments to which a hospice program would otherwise be entitled for items and services furnished by a hospice program on or after the effective date of the enforcement remedy. CMS will determine whether to impose a suspension of all or part of the payments based on the factors outlined in proposed § 488.1215 that are considered when selecting remedies. The suspension of payment is proposed at § 488.1240 to be for a period not exceed 6 months and would end when the hospice program either achieved substantial compliance or was terminated. CMS would provide the hospice program with written notice of our intent to impose a payment suspension remedy at least 2 calendar days before the effective date of the remedy in IJ situations, per proposed § 488.1225(b), or 15 calendar days before the effective date of the remedy in non-IJ situations, per proposed § 488.1230(b). The proposed notice of intent for all remedies, described at § 488.1210(e), would be used to notify a hospice program of a suspension of payment of all or part of the payments to which the hospice program would otherwise be entitled.

Additionally, section 1822(c)(5)(C)(ii) of the Act provides that a suspension of payment remedy shall terminate when CMS finds that the hospice program is in substantial compliance with the requirements specified in, or developed in accordance with, section 1861(dd) of the Act. That is, the suspension of payment remedy will end when the hospice program is determined to have corrected all condition-level deficiencies, or upon termination, whichever is earlier. We propose to codify that duration of the remedy at 488.1240(c).

j. CMPs (§ 488.1245)

We propose at § 488.1245 requirements for the imposition of CMPs. Section 1822(c)(5)(C) of the Act outlines the requirements for CMP procedures. Additionally, section 1822(c)(5)(C)(i)(I) of the Act requires that the CMP provisions under section 1128A (other than subsections (a) and (b) of the Act shall be applied to the hospice CMPs, which also must be considered when establishing the amount. CMS proposes to impose a CMP against a hospice program that is determined to be out of compliance with one or more CoPs, regardless of whether the hospice program's deficiencies pose IJ to patient health and safety. CMS could also impose a CMP for the number of days of IJ. Under section 1822(c)(5)(B)(i) of the Act, the CMP amount cannot exceed $10,000 for each day of noncompliance. Our proposals align with the imposition of CMPs authorized by section 1891(f) of the Act as set out for HHAs at § 488.845, which CMS may impose against an HHA that is determined to be out of compliance with one or more CoPs, regardless of whether the HHA's deficiencies pose IJ to patient health and safety.

In this section, we are proposing both ''per day'' and ''per instance'' CMPs at § 488.1245(a). The per day CMPs would be imposed for each day of noncompliance with the CoPs. Additionally, should a survey identify a particular instance or instances of noncompliance during a survey, we propose to impose a CMP for that instance or those individual instances of noncompliance. We propose to define ''per instance'' in § 488.1205 as a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy.

While there may be a single event that leads to noncompliance, there can also be more than one instance of noncompliance identified and more than one CMP imposed during a survey. For penalties imposed per instance of noncompliance, we are proposing penalties from $1,000 to $10,000 per instance. Such penalties would be

assessed for one or more singular events of condition-level noncompliance that were identified at the survey and where the noncompliance was corrected during the onsite survey.

Since the range of possible deficiencies is great and depends upon the specific circumstances at a particular time, it would be impossible to assign a specific monetary amount for each type of noncompliance that could be found. Thus, we believe that each deficiency would fit into a range of CMP amounts.

We are proposing that, in addition to those factors that we would consider when choosing a type of remedy proposed in § 488.1215, we would consider the following factors when determining a CMP amount:

- The size of the hospice program and its resources.
- Evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the CoPs and to ensure patient health and safety. When several instances of noncompliance would be identified at a survey, more than one per-day or per instance CMP could be imposed as long as the total CMP did not exceed $10,000 per day. In addition, a per-day and a per-instance CMP would not be imposed simultaneously for the same deficiency in conjunction with a survey.

At proposed § 488.1245, CMS would have the discretion to increase or reduce the amount of the CMP during the period of noncompliance, depending on whether the level of noncompliance had changed at the time of a revisit survey. However, section 1822(c)(5)(B)(i) of the Act specifies that the remedies shall include a CMP in an amount not to exceed $10,000 for each day of noncompliance. Therefore, we are proposing at § 488.1245(b)(2)(iii) that no CMP assessment could exceed $10,000 per day of noncompliance. To comply with sections 1822(c)(5)(B)(i) and 1822(c)(5)(C)(i) of the Act, we propose to establish a three-tier system with subcategories that would establish the amount of a CMP.

In proposed § 488.1245(b)(3), (b)(4), and (b)(5), we propose ranges of CMP amounts based on three levels of seriousness—upper, middle, and lower:

- Upper range—For a deficiency that poses IJ to patient health and safety, we would assess a penalty within the range of $8,500 to $10,000 per day of condition-level noncompliance.
- Middle range—For repeat and/or a condition-level deficiency that did not pose IJ, but is directly related to poor quality patient care outcomes, we would assess a penalty within the range of $1,500 up to $8,500 per day of noncompliance with the CoPs.
- Lower range—For repeated and/or condition-level deficiencies that did not constitute IJ and were deficiencies in structures or processes that did not directly relate to poor quality patient care, we would assess a penalty within the range of $500 to $4,000 per day of noncompliance.

The proposed CMP amounts would be subject to annual adjustments for inflation in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74). Annually adjusted amounts are published at 45 CFR part 102.

Under the proposed provisions, if CMS imposed a CMP, CMS would send the hospice program written notification of the intent to impose it, including the amount of the CMP being imposed and the proposed effective date of the sanction, under proposed §§ 488.1210(e) and 488.1245(c). Once the administrative determination is final, we propose to send a final notice to the hospice program with the amount of the penalty that was assessed; the total number of days of noncompliance (for per day CMPs); the total amount due; the due date of the penalty; and the rate of interest to be charged on unpaid balances.

Whether per instance or per day CMPs are imposed, once the hospice program has received the notice of intent to impose the CMP, it would have 60 calendar days from the receipt of the written notice of intent to either request an administrative hearing in accordance with § 498.40 or to provide notice to CMS of its intent to waive its right to an administrative hearing, in accordance to the procedures specified in proposed § 488.1245(c)(2), to receive a 35 percent reduction in the CMP amount. The CMP would be due within 15 calendar days of hospice programs' written request for waiver. If the hospice program did not respond to the notice of intent to impose a CMP within 60 calendar days of receipt, it would waive its right to a hearing. In such cases, the CMP would not be reduced by 35 percent because a hospice program must follow the procedures specified at proposed § 488.1245(c)(2) to receive the reduction.

A per-day CMP would begin to accrue as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance and would end on the date of correction of all deficiencies, or the date of termination. We propose at § 488.1245(d) that in IJ cases, if the IJ is not removed, the CMP would continue to accrue until CMS terminated the provider agreement (within 23 calendar days after the last day of the survey which first identified the IJ). Under proposed § 488.1245(d)(4), if IJ did not exist, the CMP would continue to accrue until the hospice program achieved substantial compliance or until CMS terminated the provider agreement.

As noted elsewhere, in no instance would a period of noncompliance be allowed to extend beyond 6 months from the last day of the survey that initially determined noncompliance. If the hospice program has not achieved compliance with the CoPs within those 6 months, we would terminate the hospice program. The accrual of per-day CMPs would stop on the day the hospice program provider agreement was terminated or the hospice program achieved substantial compliance, whichever was earlier. The total CMP amounts would be computed and collected after an administrative determination is final and a final notice sent to the hospice program as described in § 488.1245(e).

We also propose that for a hospice program being involuntarily terminated and for which a civil money penalty had been imposed and was still due, we would include the final notice, also known as a due and payable notice, as part of the termination notice. In other words, the information in a final notice, as described in § 488.1245(e), would be included in the termination notice.

At proposed § 488.1245(f), a CMP would become due and payable 15 calendar days from—

- The time to appeal had expired without the hospice program appealing its initial determination;
- CMS received a request from the hospice program waiving its right to appeal the initial determination;
- A final decision of an Administrative Law Judge or Appellate Board of the Departmental Appeals Board upheld CMS's determinations; or
- The hospice program was terminated from the program and no appeal request was received.

A request for a hearing would not delay the imposition of the CMP, but would only affect the collection of any final amounts due to CMS.

k. Directed Plan of Correction (§ 488.1250)

We propose at § 488.1250 to include a directed plan of correction as an available remedy. This remedy is a part of the current HHA and nursing home alternative sanction procedures and has been an effective tool to encourage correction of deficient practices. Specifically, we propose that CMS may impose a directed POC on a hospice program that is out of compliance with the CoPs. A directed POC remedy would require the hospice program to take specific actions to bring the hospice program back into compliance and correct the deficient practice(s). As indicated in § 488.1250(b)(2) a hospice program's directed POC would be developed by CMS or by the temporary manager, with CMS approval. The directed POC would set forth the outcomes to be achieved, the corrective action necessary to achieve these outcomes and the specific date the hospice program would be expected to achieve such outcomes. The hospice program would be responsible for achieving compliance. If the hospice program failed to achieve compliance within the timeframes specified in the directed POC, CMS could impose one or more additional enforcement remedies until the hospice program achieved compliance or was terminated from the Medicare program. Before imposing this remedy, CMS would provide appropriate notice to the hospice program under § 488.1210(e).

l. Directed In-Service Training (§ 488.1255)

We propose at § 488.1255, to outline the requirements for conducting directed in-service training for hospice programs with condition-level deficiencies. At proposed § 488.1255(a), directed in-service training would be required where staff performance resulted in noncompliance and it was determined that a directed in-service training program would correct this deficient practice through retraining the staff in the use of clinically and professionally sound methods to produce quality outcomes.

At § 488.1255(a)(3), we are proposing that hospice programs use in-service programs conducted by instructors with an in-depth knowledge of the area(s) that would require specific training, so that positive changes would be achieved and maintained. Hospice programs would be required to participate in programs developed by well-established education and training services. These programs would include, but not be limited to, schools of medicine or nursing, area health education centers, and centers for aging. CMS will only recommend possible training locations to a hospice program and not require that the hospice program utilize a specific school/center/provider. In circumstances where the hospice is subject to the SFP, additional technical assistance and/or resources could be made available. The hospice program would be responsible for payment for the directed in-service training for its staff. At proposed § 488.1255(b), if the hospice program did not achieve substantial compliance after such training, CMS could impose one or more additional remedies. Before imposing this remedy, CMS would provide appropriate notice to the hospice program under proposed § 488.1210(e).

m. Continuation of Payments to a Hospice Program With Deficiencies (§ 488.1260)

We propose at § 488.1260, the continuation of Medicare payments to hospice programs not in compliance with the requirements specified in section 1861(dd) of the Act over a period of no longer than 6 months in accordance with section 1822(c)(4) of the Act. The continuation of Medicare payments will continue for 6 months if—

- An enforcement remedy or remedies (with the exception of suspension of all payments) have been imposed on the hospice program and termination has not been imposed;
- The hospice program has submitted a POC which has been approved by CMS; and
- The hospice program agrees to repay the Federal government the payments received under this arrangement should the hospice program fail to take the corrective action as outlined in its approved POC in accordance with the approved plan and timetable for corrective action.

We propose these three criteria at § 488.1260(a). If any of these three requirements outlined in the Act were not met, a hospice program would not receive any Federal payments from the time that deficiencies were initially identified. CMS would also terminate the agreement before the end of the 6-month correction period, which begins on the last day of the survey, in accordance with § 488.1265 if the requirements at § 488.1260(a)(1) were not met. If any remedies were also imposed, they would stop accruing or end when the hospice program achieved compliance with all requirements, or when the hospice program's provider agreement was terminated, whichever was earlier.

Finally, if a hospice program provided an acceptable POC but could not achieve compliance with the CoPs upon resurvey within 6 months of the last day of the survey, we propose at § 488.1230(d) that we would terminate the provider agreement.

n. Termination of Provider Agreement (§ 488.1265)

At § 488.1265(a), we propose to address the termination of a hospice program's Medicare provider agreement, as well as the effect of such termination. Termination of the provider agreement would end all payments to the hospice program, including any payments that were continued at the proposed § 488.1260. Termination would also end enforcement remedies imposed against the hospice program, regardless of any proposed timeframes for the remedies originally specified. At proposed § 488.1265(b), CMS would terminate the provider agreement if—(1) the hospice program failed to correct condition-level deficiencies within 6 months unless the deficiencies constitute IJ; (2) the hospice program failed to submit an acceptable POC; (3) the hospice program failed to relinquish control of the temporary manager (if that remedy is imposed); or (4) the hospice program failed to meet the eligibility criteria for continuation of payments. At § 488.1265(d) we propose using the procedures for terminating a hospice program at § 489.53 and providing appeal rights in accordance with 42 CFR part 489. Additionally, we propose using the procedures for payments 30 days post termination for hospice programs at § 489.55. Payment is available for up to 30 days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination (§ 489.55(a)(2)).

VIII. Requests for Information

A. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Post-Acute Care Quality Reporting Programs—Request for Information

1. Background

A goal of the HH QRP is to improve the quality of health care for beneficiaries through measurement, transparency, and public reporting of data. The HH QRP contributes 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 Meaningful Measure 2.0 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, t 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 the Meaningful Measures 2.0, we are seeking feedback on our future plans to define digital quality measures for the HH QRP. We also are seeking feedback on the potential use of Fast Healthcare Interoperable Resources (FHIR) for dQMs within the HH QRP aligning where possible with other quality programs. FHIR is an 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.

2. Definition of Digital Quality Measures

We are considering adopting a standardized definition of dQMs in alignment across the QRPs including the HH QRP. We are considering in the future to propose the adoption within the HH 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.[95] 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, electronic health records (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.

3. Use of FHIR for Future dQMs in the HH QRP

Over the past years in other quality programs, we have focused on opportunities to streamline and modernize quality data collection and reporting processes, such as exploring HL7® FHIR® (*http://hl7.org/fhir*) for other quality programs. One of the first areas CMS has identified relative to improving our digital strategy is through the use of FHIR-based standards to exchange clinical information through application programming interfaces (APIs), allowing 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 HH 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 Post-Acute Care providers, including HHAs, are adopting EHRs, we are evaluating using the FHIR interfaces for accessing patient data (including standard assessments) directly from HHA 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.

4. 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 reporting programs. We are considering the future potential development and staged implementation of a cohesive portfolio of dQMs across our regulated programs, including HHQRP, 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 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, standards-based APIs). The coordination would build on the principles outlined in HHS' National Health Quality Roadmap.[96]

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, the Consensus-Based Entity under section 1890 of the Act, provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP) which reviews measures submitted to the Measures Under Consideration (MUC) list and makes recommendations on whether or not to use them in Medicare programs.'' We would coordinate with HL7's ongoing work to advance FHIR

[95] Definition taken from the CMS Quality Conference 2021.

[96] 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.*

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 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.

5. Solicitation of Comments

We seek input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital:

- What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?
- How do you currently share information with other providers and are there specific industry best practices for integrating SDOH screening into EHRs?
- 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 HHAs?
- What additional resources or tools would post-acute care settings, including but not limited to HHAs, and health IT vendors find helpful to support 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?
- Would vendors, including those that service post-acute care settings, including but not limited to HHAs, 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 Request for Information in the CY 2022 Home Health 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 Post-Acute Care Quality Reporting Programs—Request for Information

1. 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 expanding several related 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.[97] [98] [99] [100] [101] [102] [103] [104] 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 operative complications.[105] [106] [107] [108] [109] [110] 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.[111] [112] [113] [114] [115] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[116] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among black, Hispanic, and Indigenous and Native American persons relative to white persons.[117] [118]

[97] 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.

[98] 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.

[99] 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.

[100] 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.

[101] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[102] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[103] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[104] 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.

[105] 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.

[106] 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.*

[107] 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.

[108] 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.

[109] 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.

[110] 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.

[111] 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.

[112] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[113] 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.*

[114] 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.

[115] 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.

[116] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[117] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

Continued

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''.[119] One important strategy for addressing these important inequities is by 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 beneficiaries to make more informed decisions, and promoting provider accountability for health care disparities.[120] [121] 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.'' [122] 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 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 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.[123] The CMS Quality Strategy and Meaningful Measures Framework [124] include elimination of racial and ethnic disparities as a fundamental principle. Our ongoing commitment to closing the health equity gap in the HH QRP is demonstrated by seeking to adopt through future rulemaking Standardized Patient Assessment Data Elements under the HH QRP which include several social determinants of health (SDOH).

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 [125] 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.

2. Solicitation of Public Comment

Under authority of the IMPACT Act and section 1895(b)(3)(B)(v) of the Act, we are seeking comment on the possibility of expanding measure development, and the collection of other Standardized Patient Assessment Data Elements that address gaps in health equity in the HH QRP. Any potential SPADE or measure reporting related to health equity data under the HH 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:

- As finalized in the CY 2020 HH PPS final rule (84 FR 60597 through 60608), HHAs will be required to report Standardized Patient Assessment Data Elements on certain SDOH, including, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[126] CMS is seeking guidance on any additional Standardized Patient Assessment Data Elements that could be used to assess health equity in the care of HHA patients, for use in the HH QRP.
- Recommendations for how CMS can promote health equity in outcomes among HHA patients. We are also interested in feedback regarding whether including HHA-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 HHAs to identify gaps in the quality of care they provide (for example, methods similar or analogous to the *CMS Disparity Methods* [127] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures currently included in the Hospital Readmission Reduction Program (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 HHAs encounter for effective capture, use, and exchange of health information include data on ethnicity and other social determinants

[118] 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/.*

[119] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[120] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[121] 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.*

[122] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[123] 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.*

[124] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[125] 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.*

[126] In response to the COVID–19 PHE, CMS released an May 8, 2020 interim final rule with comment period (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least 2 full fiscal years after the end of the PHE.

[127] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

of health to support care delivery and decision-making.

While we will not be responding to specific comments submitted in response to this Request for Information in the CY 2022 HH 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 HH QRP requirements. Please note that any responses provided will not impact payment decisions.

IX. Revised Compliance Date for Certain Reporting Requirements Adopted for Inpatient Rehabilitation Facility (IRF) QRP and Long-Term Care Hospital (LTCH) QRP

A. Proposed Revised Compliance Date for Certain Inpatient Rehabilitation Facility (IRF) QRP Reporting Requirements

1. Background

In IFC–2 (85 FR 27550), we delayed the compliance date for certain reporting requirements under the IRF QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for IRFs to begin reporting the Transfer of Health (TOH) Information to Provider-PAC and the TOH Information to Patient-PAC measures and the requirement for IRFs to begin reporting certain Standardized Patient Assessment Data Elements from October 1, 2020 to October 1st of the year that is at least one full fiscal year after the end of the COVID–19 PHE. CMS also delayed the adoption of the updated version of the IRF Patient Assessment Instrument (PAI) V4.0 with which IRFs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements.

Under IFC–2, IRFs must use the IRF–PAI V4.0 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least one full fiscal year after the end of the COVID–19 PHE. IRFs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the IRF–PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1st of the year that is at least one full fiscal year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was intended to provide relief to IRFs from the added burden of implementing an updated instrument during the COVID–19 PHE. We wanted to provide maximum flexibilities for IRFs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC–2, we believed that the delay in collection of the TOH Information measures and Standardized Patient Assessment Data Elements would not have a significant impact on the IRF QRP. However, the COVID–19 PHE showed the important need for theses TOH Information measures and Standardized Patient Assessment Data Elements under the HH QRP. The PHE's disproportionate impact demonstrates the importance of analyzing this impact and the needs for these populations in order to improve quality of care within IRFs especially during a public health emergency.

2. Current Assessment of IRFs

To accommodate the COVID–19 PHE, CMS has provided additional guidance and flexibilities, and as a result IRFs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID–19 PHE. For example, CMS held regular ''Office Hours'' conference calls to provide IRFs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting and billing. CMS also supported PAC providers, including IRFs, by providing flexibilities in the delivery of care in response to the PHE, such as modifying the required face-to-face visits in IRF to be completed by telehealth (42 CFR 412.622(a)(3)(iv) and 412.29(e)) during the PHE for COVID–19, and waiving the post-admission physician evaluation requirement at § 412.622(a)(4)(ii). In the FY 2021 IRF PPS final rule (86 FR 48445 through 48447), CMS removed the post-admission physician evaluation requirement permanently beginning October 1, 2021. In addition, as of June 9, 2021, 63.8 percent of the adult population has received at least one vaccination, and COVID–19 cases and deaths have steadily declined over the last 30 days.[128] We also believe that much more is known about COVID–19 than at the time CMS finalized IFC–2.[129] [130] [131] [132]

Based upon other flexibilities such as the previous examples, the increase in knowledge IRF providers have about treating patients with COVID–19 [133] since finalizing IFC–2, and the trending data on COVID–19, IRFs are in a better position to accommodate reporting of the TOH measures and certain (Social Determination of Health) Standardized Patient Assessment Data Elements. Also, recent reports (not available at the time CMS IFC–2 was finalized) suggest that IRFs have the capacity to begin reporting the TOH measures and certain Social Determinant of Health (SDOH) Standardized Patient Assessment Data Elements.[134]

After evaluating the impact of the revised compliance date under IFC–2, feasibility around data collection by IRFs, and support needs of providers during the COVID–19 PHE, we have determined that IRFs now have the administrative capacity to attend training, train their staff, and work with their vendors to incorporate the updated assessment instruments, the IRF–PAI V4.0 into their operations.

We now believe that based upon the advancement of information available about COVID–19 vaccination and treatments described previously, and the importance of the data in the IRF QRP, it would be appropriate to modify the compliance date finalized in IFC–2. This may support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Throughout the Federal Government,'' issued January 20, 2021(*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

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[128] CDC COVID Data Tracker. Retrieved from: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[129] Here's Exactly Where We are with Vaccine and Treatments for COVID–19. Healthline. May 11, 2021. Retrieved from: *https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-for-covid-19.*

[130] COVID research: A year of scientific milestones. Nature. May 5, 2021. Retrieved from: *https://www.nature.com/articles/d41586-020-00502-w.*

[131] Clinical trial of therapeutics for severely ill hospitalized COVID–19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from: *https://www.nih.gov/news-events/news-releases/clinical-trial-therapeutics-severely-ill-hospitalized-covid-19-patients-begins.*

[132] COVID–19 Treatment Guidelines. National Institutes of Health. Updated April 21, 2021. Retrieved from: *https://www.covid19treatmentguidelines.nih.gov/whats-new/.*

[133] Ehsanian R, Workman J, Jones D, et al. Free-standing acute inpatient rehabilitation hospital enhanced practices and policies in response to the COVID–19 outbreak. Future Sci OA. 2021 Fe; 7(2): FSO667. Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745654/.*

[134] *https://www.healthaffairs.org/do/10.1377/hblog20201214.543463/full/.*

3. Proposal To Collect the Transfer of Health Information to Provider-PAC Measure, the Transfer of Health Information to Patient-PAC Measure, and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2022

We are proposing to revise the compliance date from IFC–2 to October 1, 2022. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the IRF–PAI assessment instrument referred to as IRF–PAI V4.0. This revised date of October 1, 2022, which is a 2-year delay from the original compliance date finalized in the FY 2020 IRF PPS final rule (84 FR 39054 through 39173), balances the support that IRFs needed during much of the COVID–19 PHE as CMS provided flexibilities to support IRFs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and TOH Information measures have been shown to be even more pressing with issues of inequities the COVID–19 PHE laid bare. This data that includes addressing SDOH provides information expected to improve quality of care for all. Consequently, we are proposing to revise the compliance date to reflect this balance and assure that data collection begins on October 1, 2022.

As stated in the FY 2020 IRF PPS final rule, CMS will provide the training and education for IRFs to be prepared for this implementation (84 FR 39119 through 39147). In addition, if CMS adopts an October 1, 2022 compliance date, CMS would release a draft of the updated version of the IRF–PAI, IRF–PAI V4.0, in early 2022.

Based upon our evaluation, we propose that IRFs would collect the Transfer of Health Information to Provider-PAC measure, the TOH Information to the Patient-PAC measure, and certain Standardized Patient Assessment Data Elements beginning October 1, 2022. Accordingly, we propose that IRFs would begin collecting data on the two TOH measures beginning with discharges on October 1, 2022. We also propose that IRFs would begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the IRF–PAI V4.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

We invite public comment on these proposals.

B. Proposed Revised Compliance Date for Certain Long-Term Care Hospital (LTCH) QRP Reporting Requirements

1. Background

In IFC–2 (85 FR 27550), we delayed the compliance date for certain reporting requirements under the LTCH QRP (85 FR 27595 through 27596). Specifically, we delayed the requirement for LTCHs to begin reporting the TOH Information to Provider-PAC measure and the TOH Information to Patient-PAC measure and the requirement for LTCHs to begin reporting certain Standardized Patient Assessment Data Elements from October 1, 2020 to October 1st of the year that is at least one full fiscal year after the end of the COVID–19 PHE. CMS also delayed the adoption of the updated version of the LTCH Continuity Assessment and Record of Evaluation (CARE) Data Set (LCDS) V5.0 with which LTCHs would have used to report the TOH measures and certain Standardized Patient Assessment Data Elements.

Under IFC–2, LTCHs must use the LCDS V5.0 to begin collecting data on the two TOH Information measures beginning with discharges on October 1st of the year that is at least one full fiscal year after the end of the COVID–19 PHE. LTCHs must also begin collecting data on certain Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1st of the year that is at least one full fiscal year after the end of the COVID–19 PHE. The delay to begin collecting data for these measures was intended to provide relief to LTCHs from the associated burden of implementing an updated instrument during the COVID–19 PHE. We wanted to provide maximum flexibilities for LTCHs to respond to the public health threats posed by the COVID–19 PHE, and to reduce the burden in administrative efforts associated with attending trainings, training their staff, and working with their vendors to incorporate the updated assessment instruments into their operations.

At the time we finalized the policy in the IFC–2, we believed that the delay in collection of the TOH Information measures, and Standardized Patient Assessment Data Elements would not have a significant impact on the LTCH QRP. However, the COVID–19 PHE showed the important need for theses TOH Information measures and Standardized Patient Assessment Data Elements under the LTCH QRP. The PHE's disproportionate impact on minority populations demonstrates the importance of analyzing this impact and the needs for these populations in order to improve quality of care within LTCHs especially during a public health emergency.

2. Current Assessment of LTCHs

To accommodate the COVID–19 PHE, CMS has provided additional guidance and flexibilities, and as a result LTCHs have had the opportunity to adopt new processes and modify existing processes to accommodate the significant health crisis presented by the COVID–19 PHE. For example, CMS held regular ''Office Hours'' conference calls to provide LTCHs regular updates on the availability of supplies, as well as answer questions about delivery of care, reporting and billing. CMS also supported PAC providers, including LTCHs, by providing flexibilities in the delivery of care in response to the PHE, such as waiving requirement at 42 CFR 482.43(a)(8), 482.61(e), and 485.642(a)(8) to provide detailed information regarding discharge planning. To address workforce concerns related to COVID–19, CMS waived requirements under 42 CFR 482.22(a)(1) through (4) to allow for physicians whose privileges would expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval. In addition, as of June 9, 2021, 63.8 percent of all the adult population has received at least one vaccination, and COVID–19 cases and deaths have steadily declined over the last 60 days.[135] We also believe that much more is known about COVID–19 than at the time CMS finalized IFC–2.[136] [137] [138] [139]

[135] CDC COVID Data Tracker. Retrieved from: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[136] Here's Exactly Where We are with Vaccine and Treatments for COVID–19. Healthline. May 11, 2021. Retrieved from: *https://www.healthline.com/health-news/heres-exactly-where-were-at-with-vaccines-and-treatments-for-covid-19.*

[137] COVID research: A year of scientific milestones. Nature. May 5, 2021. Retrieved from: *https://www.nature.com/articles/d41586-020-00502-w.*

[138] Clinical trial of therapeutics for severely ill hospitalized COVID–19 patients begins. National Institutes of Health News Releases. April 22, 2021. Retrieved from: *https://www.nih.gov/news-events/news-releases/clinical-trial-therapeutics-severely-ill-hospitalized-covid-19-patients-begins.*

Based upon other flexibilities such as the previous examples, the increase in knowledge LTCH providers have about treating patients with COVID–19 [140] since finalizing IFC–2, and the trending data on COVID–19, LTCHs are now in a better position to accommodate reporting of the TOH measures and certain Standardized Patient Assessment Data Elements.[141]

After evaluating the impact of the revised compliance date under IFC–2, feasibility around data collection in LTCHs, and support needs of providers during the COVID–19 PHE, we have determined that LTCHs now have the administrative capacity to attend trainings, train their staff, and work with their vendors to incorporate the updated assessment instrument, the LCDS V5.0 into their operations.

We now believe that based upon the advancement of information available about COVID–19 vaccination and treatments described previously, and the importance of the data to the LTCH QRP it would be appropriate to modify the compliance date finalized in IFC–2. This may support future activities under Executive Order 13985, entitled ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' issued January 20, 2021 (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government).*

3. Proposal To Collect the Transfer of Health Information to Provider-PAC Measure, the Transfer of Health Information to Patient-PAC Measure, and Certain Standardized Patient Assessment Data Elements Beginning October 1, 2022

We are proposing to revise the compliance date from IFC–2 to October 1, 2022. This revised date would begin the collection of data on the Transfer of Health Information to Provider-PAC measure and Transfer of Health Information to Patient-PAC measure, and certain Standardized Patient Assessment Data Elements on the updated version of the LCDS V5.0. This revised date of October 1, 2022, which is a two-year delay from this original compliance date finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), balances the support that LTCHs needed during much of the COVID–19 PHE as CMS provided flexibilities to support LTCHs along with the need to collect this important data.

The need for the Standardized Patient Assessment Data Elements and TOH Information measures have been shown to be even more pressing with issues of inequities the COVID–19 PHE laid bare. This data that includes addressing SDOH provides information expected to improve quality of care for all. Consequently, we are proposing to revise the compliance date to reflect this balance and assure that data reporting begins on October 1, 2022.

As stated in the FY 2020 IPPS/LTCH PPS final rule, CMS will provide the training and education for LTCHs to be prepared for this implementation (84 FR 42540 through 42560). In addition, if CMS adopts an October 1, 2022 compliance date, CMS would release a draft of the updated version of the LCDS, LCDS V5.0, in early 2022.

Based upon our evaluation, we propose that LTCHs would collect the Transfer of Health Information to Provider-PAC measure, the Transfer of Health Information to the Patient-PAC measure, and certain Standardized Patient Assessment Data Elements, beginning on October 1, 2022. We propose that accordingly, LTCHs would begin collecting data on the two TOH measures beginning with discharges on October 1, 2022. We also propose that LTCHs would begin collecting data on the six categories of Standardized Patient Assessment Data Elements on the LCDS V5.0, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

We invite public comment on these proposals.

X. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act 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 Paperwork Reduction Act 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).

B. Collection of Information Requirements

1. HH QRP

In section IV.C. of this propose rule, we propose changes and updates to the HH QRP. We believe that the burden associated with the HH QRP proposals is the time and effort associated with data quality and reporting. As of March 1, 2021, there are approximately 11,400 HHAs reporting quality data to CMS under the HH QRP. For the purposes of calculating the costs associated with the information collection requirements, we obtained mean hourly wages for these from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 35.

[139] COVID–19 Treatment Guidelines. National Institutes of Health. Updated April 21, 2021. Retrieved from: *https://www.covid19treatmentguidelines.nih.gov/whats-new/.*

[140] Ehsanian R, Workman J, Jones D, et al. Free-standing acute inpatient rehabilitation hospital enhanced practices and policies in response to the COVID–19 outbreak. Future Sci OA. 2021 Fe; 7(2): FSO667. Retrieved from: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7745654/.*

[141] *https://www.healthaffairs.org/do/10.1377/hblog20201214.543463/full/.*

TABLE 35: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$38.47	$38.47	$76.94
Physical therapists HHAs	29-1123	$44.08	$44.08	$88.16
Speech-Language Pathologists (SLP)	29-1127	$40.02	$40.02	$80.04
Occupational Therapists (OT)	29-1122	$42.06	$42.06	$84.12
Medical Dosimetrists, Medical Records Specialists, and Health Technologists and Technicians	29-2098	$23.21	$23.21	$46.42

In section IV.C.4.a. of the proposed rule, we are proposing to remove the Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care measure under removal factor 1, measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. Additionally, we are proposing to remove the OASIS item M2016 used to calculate this measure. This item removal will result in a decrease in overall burden.

In sections IV.C.4.b. and c. of the proposed rule, we are proposing to adopt the Home Health Within Stay Potentially Preventable Hospitalization claims-based measure. We are proposing to replace the Acute Care Hospitalization During the First 60 Days of HH (NQF #0171) measure and the Emergency Department Use without Hospitalization During the First 60 Days of HH (NQF #0173) measure with the Within Stay Potentially Hospitalization measure beginning with the CY 2023 HH QRP under our measure removal factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available. Because the measures are claims-based, the replacement/removal will not impact collection of information.

Therefore, we are proposing a net reduction of 1 data element at the Discharge from Agency time point and 1 data element at the Transfer of Care time point associated with OASIS item (M2016) collection as a result of the measure removal. We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimate that there would be a reduction in clinician burden per OASIS assessment of 0.3 minutes at Discharge from Agency and 0.3 minutes at Transfer of Care.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OTs) or speech language pathologists (SLT/SP). Data from 2020 show that the OASIS is completed by RNs (approximately 76.5 percent of the time), PTs (approximately 20.78 percent of the time) and other therapists including OTs and SLP/STs (approximately 2.72 percent of the time). Based on this analysis, we estimated a weighted estimated clinician average hourly wage of $79.41, inclusive of fringe benefits using the wage data from Table 35. Individual providers determine the staffing necessary.

Table 36 shows the total number of assessments submitted in CY 2020 and estimated costs at each time point.

TABLE 36: CY 2020 OASIS SUBMISSIONS AND ESTIMATED COSTS, BY TIME POINT

Time Point	CY 2020 Assessments Completed	Estimated Cost ($)
Transfer of Care	1,788,100	$4,259,791
Discharge from agency	5,168,903	$228,832,891
TOTAL	**6,957,003**	**$233,092,681**

* Estimated Burden ($) at each Time-Point = (# CY 2020 Assessments Completed) x (clinician burden [min]/60) x ($79.41 [weighted clinician average hourly wage]). Excluding M2016, there are 1.8 minutes to complete transfer of care 6 transfer of care data elements and 33.45 minutes to complete 123 data elements at discharge.

Based on the data in Table 35 and Table 36 for the 11,400 active Medicare-certified HHAs, we estimate the total decrease in costs associated with the changes in the HH QRP at approximately $242 per HHA annually or $2,762,277 for all HHAs. This corresponds to an estimated decrease in clinician burden associated proposed changes to the HH QRP of approximately 3.1 hours per HHA or approximately 34,785 hours for all HHAs. This decrease in burden would be accounted for in the information collection under OMB control number 0938–1279 (Expiration date: 12/31/2021).

In section IV.C. of this proposed rule, we propose a revised compliance date for certain reporting requirements adopted for the HH QRP. The burden for the proposed revision to the HH QRP requirements as adopted in the CY 2020 HH PPS final rule (84 FR 60632 through 60642) has been accounted for in OMB control number 0938–1279. Therefore, this proposal would not affect the information collection burden already established.

2. ICRs Regarding Revised Compliance Dates for Certain Reporting Requirements

a. IRF QRP Requirements

In section VIII.A. of this proposed rule, we propose to revise the compliance date for certain reporting requirements adopted for the IRF QRP. We believe that the burden associated with the IRF QRP proposal is the time and effort associated with reporting quality data. As of April 4, 2021, there are approximately 1,109 IRFs reporting quality data to CMS. The burden for the proposed revision to the IRF QRP requirements as adopted in the FY 2020 IRF PPS final rule (84 FR 39165 through 39172) has been accounted for in OMB control number 0938–0842 (Expiration date: 12/31/2022). Therefore, this proposal would not affect the information collection burden for the IRF QRP.

b. LTCH QRP Requirements

In section VIII.B. of this proposed rule, we propose a revised compliance date for certain reporting requirements adopted for the LTCH QRP. We believe that the burden associated with the LTCH QRP proposal is the time and effort associated with reporting quality data. As of April 21, 2021, there are approximately 363 LTCHs reporting quality data to CMS. The burden for the proposed revision to the LTCH QRP requirements as adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42602 through 42656) has been accounted for in OMB control number 0938–1163 (expiration12/31/2022). Therefore, this proposal would not affect the information collection burden for the LTCH QRP.

3. ICRs Related to the Changes in the Home Health CoPs

a. ICRs Related to the Virtual Supervision of HHA Aides

In section IV.D. of this propose rule, we would revise § 484.80(h)(1) to specify that if a patient is receiving skilled care (patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services), the home health aide supervisor (RN or therapist) must complete a supervisory assessment of the aide services being provided, either onsite (that is, an in person visit) or using interactive telecommunications systems no less frequently than every 14 days. The home health aide would not have to be present during the supervisory assessment. The use of interactive telecommunications systems for the aide supervisory assessment must not exceed 2 times per HHA in a 60-day period. We propose to revise § 484.80(h)(2) to specify that, if a patient is not receiving skilled care, the RN must make an in-person supervisory visit to the location where the patient is receiving care, once every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs. The home health aide does not need to be present during this visit. We are also proposing that the RN would make a semi-annual on-site (in-person) visit to the location where a patient is receiving care in order to observe and assess the home health aide while he or she was performing care. This semi-annual supervisory visit of the aide performing care would replace the current every 60-day requirement of direct supervision of the aide performing care. Section 484.80(h) also requires HHAs to document the supervision of home health aides in accordance with specified timeframes. In addition, we believe the modification proposed at § 484.80(h)(3) includes retraining and competency evaluations related to both the skills verified as deficient and to any related skills will not add any information collection burden and will enhance the provisions of safe, quality home health services. In accordance with the implementing regulation of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the proposed revisions to the requirements at 484.80(h) are exempt from the PRA. We believe competency evaluations are a usual and customary business practice and we state as such in the information collection request associated with the Home Health CoPs (OMB control number: 0938–1299/Expiration: 06/30/2021). Therefore, we are not proposing to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 484.80(h), but we request public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary, and would be incurred by home health staff even absent this regulatory requirement.

b. ICRs Related to Permitting Occupational Therapist To Complete the Initial and Comprehensive Assessments for Home Health Agencies

In section IV.D. of this proposed rule, we would implement Division CC, section 115 of CAA 2021 by proposing conforming regulations text changes at § 484.55(a)(2) and (b)(3) permitting the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are also not initially on the home health plan of care. These changes permit occupational therapists to complete these assessments even though the need for occupational therapy would not establish the patient's eligibility for the Medicare home health benefit. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe that both the existing requirements and the proposed revisions to the requirements at § 484.55(a)(2) and (b)(3) are exempt from the PRA. We believe patient assessment are a usual and customary business practice and we state such in the information collection request associated with the OASIS data set, which comprises the core of the patient assessment and is currently approved under OMB control number: 0938–1279 (Expiration date: 06/30/2024). Therefore, we are not proposing to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 484.55(a)(2) and (b)(3), but we request public comment on our determination that the time and effort necessary to comply with these evaluation requirements is usual and customary and would be incurred by home health staff even absent this regulatory requirement.

4. ICRs Regarding Medicare Provider and Supplier Enrollment Provisions

We do not anticipate any information collection burden associated with our provider and supplier enrollment proposals. Since most of these proposals have been in subregulatory guidance for a number of years and we are simply incorporating them into regulation, there would not be any change in burden on the provider community. Those provisions that are not in subregulatory guidance do not implicate information collection requirements.

5. ICRs Regarding Survey and Enforcement Requirements for Hospices

a. Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 37 presents the mean hourly wage, the cost of fringe benefits and

overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 37: U.S. BUREAU OF LABOR STATISTICS' MAY 2020 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wages
Computer and Information Analysts	15-1210	$48.40	$48.40	$96.80
Home Health and Personal Care Aides; and Nursing Assistants, Orderlies, and Psychiatric Aides	31-1100	$14.10	$14.10	$28.20
Medical or Health Services Manager	11-9111	$55.37	$55.37	$110.74
Registered Nurse (RN)	29-1141	$38.47	$38.47	$76.94

b. Application and Re-Application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require AOs with CMS-approved hospice programs to include a statement of deficiencies, (that is, the Form CMS–2567 or a successor form) to document findings of the hospice Medicare CoPs and to submit such in a manner specified by CMS. The current information collection request for the form CMS–2567, titled ''Statement Of Deficiencies And Plan Of Correction'' (OMB control number 0938–0391/ Expiration date: 6/30/2021) does not account for any information collection related burden associated with AO use. As discussed in the preamble of this proposed rule, in section VII.B.2.b. of this proposed rule, we note that the currently approved Form CMS–2567 does not include a place for the name of the AO completing the survey and AOs are not addressed in the instructions. These are minor revisions to the form but we will submit the revised information collection request to OMB for approval.

We discussed in the preamble section VII.B.2.b. of this proposed rule, how AOs conduct hospice program surveys and gather deficiency findings into a report that is provided to the surveyed hospice. CMS believes the statutory requirement and subsequent proposed rule for the inclusion of Form CMS–2567 would not add significant burden to AOs as they already develop deficiency finding reports as part of their existing process just in a different format. We note that AOs would need to make a one-time update to their existing proprietary electronic documentation systems to include the Form CMS–2567. We estimate that this task would be performed by a computer and information analyst. According to the U.S Bureau of Labor statistics, the mean hourly wages for a computer and information analyst is $48.40. This wage adjusted for the employer's fringe benefits and overhead would be $96.80.

We estimate that it would take at least two persons working on a full-time basis for 3 days for the AO staff to revise their system to add the required Form CMS–2567. Therefore, we estimate that the total time required for the two team members to perform this task would be 48 hours. As of March 2021, there are three AOs that accredit Medicare certified hospice programs. The total time burden across these three AOs would be 144 hours.

We estimate that the cost burden related to the work performed by two computer and information analysts would be $4,646.50 (24 hours × $193.60 ($96.80 × 2)). The total cost across the three AOs would be $13,939.50 (3 AOs × $4,646.50). The burden associated with this requirement will be submitted to OMB under OMB control number 0938–NEW (Expiration date: pending). We seek comments that would help us to develop an accurate estimate of the cost and time burden that would result from this collection of information.

These are minor revisions to the form; however, as required under the PRA we will be seeking OMB approval for a revised version of the form. Please note, we will be seeking OMB approval via the required notice and comment periods but they will be separate from this proposed rulemaking. The revised information collection request will be announced in the **Federal Register** and the public will have the opportunity to review and comment as necessary.

c. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

We proposed at § 488.1115, to require AO surveyors to complete the online hospice basic training. As discussed in the preamble section VII.B.2.d. of this proposed rule, we note there are multiple online training programs available to SA surveyors on the CMS QSEP website. These courses are self-paced, slide based presentations and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training courses varies depending on the pace at which the surveyor is able to read through or listen to the presentation and complete the training. Duration time is based on the estimate that it takes learners approximately 2 minutes per slide. This information is publicly available on *https://qsep.cms.gov/welcome.aspx.* We proposed that each AO hospice program surveyor take the hospice basic training course that has an average completion time of 24 hours. Completion time could be more or less depending upon the learner's familiarity with the content and overall learning style. Therefore, a hospice program AO surveyor would incur a time burden of approximately 24 hours for the completion of this CMS surveyor training course.

The AOs that accredit Medicare certified hospice programs would incur a cost burden for the wages of their surveyors for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as RNs.

As noted, we estimated that it would take approximately 24 hours for each AO surveyor to complete the hospice basic training online surveyor course. Therefore, the AO would incur wages in the amount of $1,846.56 per each surveyor that completes the CMS online surveyor training (24 hours × $76.94).

We are not able to precisely estimate total time and cost burden to each AO for the wages incurred for the time spent by all surveyors from each of the three hospice program AOs to take the CMS online surveyor training course, because each AO varies greatly in organization

size, number of accreditation programs approved by CMS, and total surveyor cadre numbers. There are no regulatory requirements for AOs to report to CMS on the number of surveyors within their organization nor information on how many of those surveyors survey each type of program approved by CMS. CMS notes there is a wide variety of total surveyor cadre numbers across all three AOs, based on information CMS has gathered from confidential numbers, voluntarily provided by some of the AOs to CMS, as part of their deeming authority application documents as well as information found online via a search of each AOs public website. Variation is generally based on the associated number of CMS-approved accreditation programs the AO possesses. For example, AOs who accredit only one provider or supplier type generally have about 25 surveyors while AOs with multiple programs have surveyor numbers well over 300 thereby skewing the ability to estimate an accurate time burden that represents the overall group. Because of this wide range CMS is estimating near the middle, using 100 total surveyors per AO. If we estimate that each AO has approximately 100 total surveyors, the estimated time burden to each AO associated with this requirement would be 2,400 hours (24 hours × 100 surveyors).

The estimated cost burden to each AO (that accredits Medicare-certified hospice programs) associated with this requirement would be $184,656 (2,400 hours × $76.94 per hour). The burden associated with this requirement will be submitted to OMB under OMB control number 0938–NEW (Expiration date: pending).

As of March 2021, there are three AOs that accredit Medicare-certified hospice programs. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 7,200 hours (2,400 hours × 3 AOs).

The estimated cost across all AOs (that accredit Medicare-certified hospice programs) would be $553,968 ($184,656 × 3 AOs). We request feedback on the total number of AO hospice program surveyors we should consider, especially if our estimate of 100 is grossly under or over estimated.

6. HHVBP Expanded Model

In section III. of this proposed rule, we propose policies necessary to implement the expanded Home Health Value-Based Purchasing Model (see proposed §§ 484.340 through 484.375), which is aimed at increasing quality and reducing spending through payment adjustments based on quality performance for HHAs nationwide. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the HHVBP expanded model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA does not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

C. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS–1747–P) and, where applicable, the preamble section, and the ICR section. See this rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

XI. Regulatory Impact Analysis

A. Statement of Need

1. HH PPS

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act requires the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115–123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of service, for 30-day periods beginning on and after January 1, 2020. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments.

2. HHVBP Model

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis), through notice and comment rulemaking, the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net program spending; and (3) the Secretary determines that the expansion would

not deny or limit the coverage or provision of benefits. On January 8, 2021, we announced that the HHVBP Model (the original Model) had been certified for expansion nationwide,[142] as well as our intent to expand the Model through notice and comment rulemaking beginning no sooner than CY 2022. The original Model has resulted in an average 4.6 percent improvement in home health agencies' quality scores as well as average annual savings of $141 million to Medicare. The CMS Chief Actuary has determined that HHVBP Model would reduce Medicare expenditures if expanded to all States.

If finalized, all Medicare-certified HHAs in the 50 States, District of Columbia and the territories would be required to participate in the expanded HHVBP Model beginning January 1, 2022. These HHAs would compete on value based on an array of quality measures that capture the services provided by HHAs. The savings impacts related to the HHVBP Model expansion are estimated at a total projected 5-year gross FFS savings, CYs 2022 through 2026, of $3,154,000,000. The savings under the original Model are already assumed in the baseline and therefore are not included in the 5-year gross estimated savings under HHVBP Model expansion. As previously mentioned in section III.A.3.b. of this proposed rule, under the expanded duration and scope of this Model, we would continue to examine whether the proposed adjustments to the Medicare payment amounts that would otherwise be made to competing HHAs would result in statistically significant improvements in the quality of care being delivered to Medicare beneficiaries, as well as reductions in Medicare spending.

3. HH QRP

Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data in accordance with the requirements of the HH QRP and requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase.

4. Effects of the Changes to the Home Health CoPs

a. Virtual Supervision of HHA Aides

In section IV.D. of this rule, we propose to revise the CoPs for home health agencies. Specifically, in section IV.D. of this rule, we propose to revise the home health aide supervision requirements to allow for virtual supervision. The burden may be reduced for providers by improving the efficiency of the training and supervision of home health aides. We are also adding the requirement that the skills related to any deficient skills be addressed. We believe the burden associated with addressing skills related to those identified as deficient skills is minimal. Moreover, supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and State and Federal compliance purposes constitutes a usual and customary business practice. Therefore, the regulatory impact is negligible.

b. Permitting Occupational Therapists To Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

In accordance with Division CC, section 115 of CAA 2021, we are proposing conforming regulations text changes to permit the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are also not ordered. We do not expect any increase in burden for any of these modifications. In fact, for home health agencies, burden may be reduced by expanding the type of therapy discipline able to complete the initial and comprehensive assessments, in some circumstances, for Medicare patients. We do not expect the changes for these provisions will cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

5. Medicare Coverage of Home Infusion Therapy

Section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act, requires the Secretary to establish a home infusion therapy services payment system under Medicare. This payment system requires a single payment to be made to a qualified home infusion therapy supplier for items and services furnished by a qualified home infusion therapy supplier in coordination with the furnishing of home infusion drugs. Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment is for each infusion drug administration calendar day in the individual's home. The Secretary shall, as appropriate, establish single payment amounts for types of infusion therapy, including to take into account variation in utilization of nursing services by therapy type. Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the Physician Fee Schedule (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting, except such single payment shall not reflect more than 5 hours of infusion for a particular therapy in a calendar day. Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted by a geographic wage index. Finally, section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier payments and other factors as deemed appropriate by the Secretary, and are required to be made in a budget neutral manner. Section 1834(u)(3) of the Act specifies that annual updates to the single payment are required to be made beginning January 1, 2022, by increasing the single payment amount by the percentage increase in the CPI–U for all urban consumers for the 12-month period ending with June of the preceding year, reduced by the productivity adjustment. The unit of single payment for each infusion drug administration calendar day, including the required adjustments and the annual update, cannot exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services if furnished in a physician's office, and the single payment amount cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. Finally, Division N, section 101 of CAA 2021 amended section 1848(t)(1) of the Act and modified the CY 2021 PFS rates by providing a 3.75 percent increase in PFS payments only for CY 2021.

6. Medicare Provider and Supplier Enrollment Provisions

Our proposals concerning Medicare provider and supplier enrollment are needed to (1) incorporate various subregulatory policies into 42 CFR part 424, subpart P, and (2) clarify several policy issues. We believe these proposals would increase transparency by allowing the provider community to furnish public comments on them while eliminating uncertainty regarding the scope and applicability of the provisions in question.

[142] *https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.*

7. Survey and Enforcement Requirements for Hospice Providers

In accordance with section 407 of the CAA 2021, we propose conforming regulations which establish new hospice program survey and enforcement requirements. We believe these proposals not only meet the statutory requirements but would increase public transparency by encouraging a consistent survey and enforcement process and providing the public with information necessary to make an informed decision regarding where they seek high quality, safe care hospice program organizations for themselves or loved ones.

B. Overall Impact

We have examined the impacts of this 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. 801(a)(1)(B)(i)).

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. Therefore, we estimate that this rule is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that presents our best estimate of the costs and benefits of this rule.

The following summary provides the economic impact estimates associated with the provisions of this proposed rule:

1. Overall Impacts—HH PPS

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The net transfer impact related to the changes in payments under the HH PPS for CY 2022 is estimated to be $310 million (1.7 percent).

2. Overall Impacts—Home Health Value Based Purchasing Model Expansion

Beginning in CY 2024 and in each succeeding payment year under the expanded HHVBP Model, we would adjust the final claim payment amount for a home health agency for a date of service in the calendar year by an amount up to the maximum applicable percent. For purposes of this proposed rule, we have limited our analysis of the economic impacts to the value-based incentive payment adjustments. Under the expanded Model design, the incentive payment adjustments would be limited to the total payment reductions to home health agencies included in the expanded Model, such that in aggregate, payment reductions to lower-performing HHAs would approximate the aggregate payment increases to higher-performing HHAs. Overall, the impact of this rule is estimated at $3,154,000,000 for CYs 2022 to 2026, though these savings result primarily from reductions in utilization of services, including acute hospital admissions and skilled nursing facility (SNF) visits. The expanded Model would test the effect on quality and costs of care by applying payment adjustments based on HHAs' performance on quality measures.

C. Detailed Economic Analysis

1. HH PPS

This rule proposes updates to Medicare payments under the HH PPS for CY 2022. The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case mix. This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based primarily on Medicare claims data for periods ending on or before December 31, 2020. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 38 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2022. For this analysis, we used an analytic file with linked CY 2020 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2020. The first column of Table 38 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the Case-Mix Weights Recalibration Neutrality Factor.

The fourth column shows the payment effects of updating to the CY 2022 wage index. The fifth column shows the payment effects of the CY 2022 rural add-on payment provision in statute. The sixth column shows the payment effects of the proposed CY 2022 home health payment update percentage and the last column shows the combined effects of all the proposals in this rule.

Overall, it is projected that aggregate payments in CY 2022 would increase by 1.7 percent. As illustrated in Table 38, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2022 wage index, the percentage of total HH PPS payments that were subject to the

LUPA or paid as outlier payments, and the degree of Medicare utilization.

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TABLE 38: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2022

	Number of Agencies	Case-Mix Weights Recalibration Neutrality Factor	CY 2022 Updated Wage Index	CY 2022 Rural Add-On	CY 2022 Proposed HH Payment Update Percentage	Total
All Agencies	**9,401**	**0.0%**	**0.0%**	**-0.1%**	**1.8%**	**1.7%**
Facility Type and Control						
Free-Standing/Other Vol/NP	939	0.4%	-0.3%	-0.1%	1.8%	1.8%
Free-Standing/Other Proprietary	7,588	-0.2%	0.1%	-0.1%	1.8%	1.6%
Free-Standing/Other Government	183	0.8%	0.1%	-0.4%	1.8%	2.3%
Facility-Based Vol/NP	487	0.6%	-0.1%	-0.2%	1.8%	2.1%
Facility-Based Proprietary	50	0.3%	0.0%	-0.2%	1.8%	1.9%
Facility-Based Government	154	0.5%	0.4%	-0.3%	1.8%	2.4%
Subtotal: Freestanding	8,710	0.0%	0.0%	-0.1%	1.8%	1.7%
Subtotal: Facility-based	691	0.5%	-0.1%	-0.2%	1.8%	2.0%
Subtotal: Vol/NP	1,426	0.5%	-0.3%	-0.1%	1.8%	1.9%
Subtotal: Proprietary	7,638	-0.2%	0.1%	-0.1%	1.8%	1.6%
Subtotal: Government	337	0.6%	0.3%	-0.3%	1.8%	2.4%
Facility Type and Control: Rural						
Free-Standing/Other Vol/NP	224	0.3%	-0.1%	-0.7%	1.8%	1.3%
Free-Standing/Other Proprietary	798	-0.2%	0.0%	-0.3%	1.8%	1.3%
Free-Standing/Other Government	122	0.8%	0.2%	-0.8%	1.8%	2.0%
Facility-Based Vol/NP	216	0.6%	-0.1%	-0.7%	1.8%	1.6%
Facility-Based Proprietary	19	0.3%	-0.3%	-0.6%	1.8%	1.2%
Facility-Based Government	114	0.5%	0.5%	-0.6%	1.8%	2.2%
Facility Type and Control: Urban						
Free-Standing/Other Vol/NP	715	0.4%	-0.3%	0.0%	1.8%	1.9%
Free-Standing/Other Proprietary	6,790	-0.2%	0.1%	0.0%	1.8%	1.7%
Free-Standing/Other Government	61	0.7%	0.1%	-0.1%	1.8%	2.5%
Facility-Based Vol/NP	271	0.6%	-0.1%	-0.1%	1.8%	2.2%
Facility-Based Proprietary	31	0.3%	0.2%	0.0%	1.8%	2.3%
Facility-Based Government	40	0.4%	0.3%	0.0%	1.8%	2.5%
Facility Location: Urban or Rural						
Rural	1,493	0.0%	0.0%	-0.4%	1.8%	1.4%
Urban	7,908	0.0%	0.0%	0.0%	1.8%	1.8%
Facility Location: Region of the Country (Census Region)						
New England	323	0.3%	-0.7%	-0.1%	1.8%	1.3%
Mid Atlantic	428	0.8%	-0.6%	-0.1%	1.8%	1.9%
East North Central	1,588	0.0%	-0.2%	-0.2%	1.8%	1.4%
West North Central	618	0.3%	0.2%	-0.3%	1.8%	2.0%
South Atlantic	1,530	0.3%	0.5%	-0.1%	1.8%	2.5%
East South Central	370	-0.1%	-0.6%	-0.1%	1.8%	1.0%
West South Central	2,219	-0.3%	-0.3%	0.0%	1.8%	1.2%
Mountain	674	-0.1%	0.0%	-0.1%	1.8%	1.6%
Pacific	1,609	-0.6%	0.5%	0.0%	1.8%	1.7%
Outlying	42	0.7%	-1.4%	-0.4%	1.8%	0.7%
Facility Size (Number of 30-day Periods)						
< 100 periods	1,998	0.2%	0.0%	-0.1%	1.8%	1.9%
100 to 249	1,512	-0.2%	0.0%	-0.1%	1.8%	1.5%

	Number of Agencies	Case-Mix Weights Recalibration Neutrality Factor	CY 2022 Updated Wage Index	CY 2022 Rural Add-On	CY 2022 Proposed HH Payment Update Percentage	Total
250 to 499	1,711	-0.3%	0.1%	-0.1%	1.8%	1.5%
500 to 999	1,887	-0.3%	0.1%	-0.1%	1.8%	1.5%
1,000 or More	2,293	0.1%	-0.1%	-0.1%	1.8%	1.7%

Source: CY 2020 Medicare claims data for periods with matched OASIS records (only) starting and ending in CY2020 (as of Mar 15, 2021).

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

2. Impacts for the Expanded HHVBP Model

Based on proposals discussed in section III.A. of this proposed rule, Tables G6 and G7 display our analysis of the distribution of possible payment adjustments using 2019 data as the performance year, while Table 39 provides information on the estimated impact of this proposed expansion. We note that this impact analysis is based on the aggregate value of savings associated with all Medicare-certified HHAs in each State, territory, and the District of Columbia.

Value-based incentive payment adjustments for the estimated 7,500-plus HHAs that would qualify to compete in the proposed HHVBP Model expansion based on the CY 2019 data stratified by size, as defined in section III.F. of this proposed rule. For example, Table 40 shows California has 69 HHAs that do not provide services to enough beneficiaries to be required to complete HHCAHPS surveys, and therefore, would be considered to be in the smaller-volume cohort under the proposed Model expansion. Using 2019 performance year data and the proposed payment adjustment of 5-percent, based on 8 outcome measures, the smaller-volume HHAs in California would have a mean payment adjustment of positive 0.042 percent. Only 10-percent of home health agencies would be subject to downward payment adjustments of more than minus 3.139 percent (−3.139 percent). The next columns provide the distribution of scores by percentile. We see that the value-based incentive percentage payments for smaller-volume home health agencies in California range from −3.139 percent at the 10th percentile to +3.899 percent at the 90th percentile, while the value-based incentive payment at the 50th percentile is −0.607 percent. The smaller-volume HHA cohort table identifies that some locations do not have any qualifying HHAs in the smaller-volume cohort, including Connecticut, the District of Columbia, and Delaware.

The next columns provide the distribution of scores by percentile. We see that the value-based incentive percentage payments for smaller-volume home health agencies in California range from −3.139 percent at the 10th percentile to +3.899 percent at the 90th percentile, while the value-based incentive payment at the 50th percentile is −0.607 percent.

The smaller-volume HHA cohort table identifies that some locations do not have any qualifying HHAs in the smaller-volume cohort, including Connecticut, the District of Columbia, and Delaware.

Table 41 provides the payment adjustment distribution based on proportion of dual eligible beneficiaries, average case mix (using HCC scores), proportion that reside in rural areas, as well as HHA organizational status. To define cutoffs for the ''percentage of dual eligible beneficiaries,'' low, medium, or high percentage dual-eligible are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of percent dual eligible beneficiaries, respectively, across HHAs in CY 2019. To define case mix cutoffs, low, medium, or high acuity are also based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2019. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries' core-based statistical area (CBSA) urban versus rural designation. We would note that, based on 2019 data, a higher proportion of dually-eligible beneficiaries served is associated with better performance.

TABLE 39. ESTIMATED GROSS FFS SAVINGS UNDER EXPANDED HHVBP MODEL CYs 2022-2026

CY 2022	CY 2023		CY 2024	CY 2025	CY 2026
$334,000,000	$674,000,000		$670,000,000	$713,000,000	$761,000,000

TABLE 40: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS (Based on a maximum 5 percent payment adjustment)

Smaller-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)	(0.646)
AL	1	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601	1.601
AR	2	0.794	(2.454)	(2.454)	(2.454)	(2.454)	0.794	4.041	4.041	4.041	4.041
AZ	2	0.710	(2.446)	(2.446)	(2.446)	(2.446)	0.710	3.866	3.866	3.866	3.866
CA	69	0.042	(3.139)	(2.503)	(1.748)	(1.495)	(0.607)	0.878	1.586	2.605	3.899
CO	4	0.127	(2.367)	(2.367)	0.445	0.445	0.572	0.698	0.698	1.733	1.733
CT	0										
DC	0										
DE	0										
FL	51	0.756	(3.080)	(1.928)	(1.016)	(0.014)	0.612	1.482	3.336	3.935	5.000
GA	0										
GU	0										
HI	0										
IA	7	(0.840)	(2.816)	(1.831)	(1.641)	(1.641)	(1.422)	(1.096)	(1.096)	(0.082)	3.009
ID	1	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)	(2.206)
IL	61	0.652	(3.275)	(2.451)	(1.614)	(0.772)	1.170	1.856	2.794	3.627	5.000
IN	11	0.596	(2.821)	(1.241)	(0.390)	0.683	0.729	1.028	1.367	2.944	3.059
KS	4	0.321	(3.256)	(3.256)	(1.255)	(1.255)	0.031	1.317	1.317	4.476	4.476
KY	0										
LA	0										
MA	5	(0.709)	(4.469)	(4.107)	(3.744)	(2.321)	(0.898)	0.489	1.876	2.784	3.692
MD	2	0.345	(2.576)	(2.576)	(2.576)	(2.576)	0.345	3.265	3.265	3.265	3.265
ME	1	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)	(2.179)
MI	52	0.896	(2.662)	(2.081)	(0.494)	0.397	1.011	1.790	2.787	3.255	4.814
MN	7	(2.227)	(4.577)	(4.453)	(3.677)	(3.677)	(3.244)	(0.514)	(0.514)	(0.480)	1.359
MO	7	(1.996)	(4.370)	(3.431)	(3.223)	(3.223)	(2.419)	(2.106)	(2.106)	0.176	1.399
MP	0										
MS	0										
MT	2	2.049	(0.847)	(0.847)	(0.847)	(0.847)	2.049	4.944	4.944	4.944	4.944
NC	4	(0.681)	(2.371)	(2.371)	(1.204)	(1.204)	(0.473)	0.259	0.259	0.592	0.592
ND	0										
NE	8	(0.751)	(4.403)	(3.062)	(2.029)	(0.282)	(0.165)	(0.047)	0.750	1.211	1.851
NH	1	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)	(4.501)
NJ	0										
NM	3	0.394	(1.562)	(1.562)	(1.562)	(0.746)	(0.746)	(0.746)	3.490	3.490	3.490
NV	8	(0.691)	(3.671)	(3.033)	(1.997)	(1.029)	(0.905)	(0.780)	(0.181)	0.164	5.000
NY	0										
OH	8	(2.409)	(4.307)	(4.178)	(3.890)	(3.739)	(3.618)	(3.497)	(1.041)	(0.905)	2.286
OK	8	(2.008)	(4.351)	(3.004)	(2.942)	(2.347)	(2.068)	(1.788)	(1.747)	0.042	0.076

Smaller-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
OR	1	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)	(0.938)
PA	9	(1.965)	(4.263)	(4.023)	(3.537)	(3.056)	(2.969)	(1.039)	(0.725)	0.543	1.385
PR	0										
RI	0										
SC	0										
SD	4	(1.081)	(3.754)	(3.754)	(2.073)	(2.073)	(1.170)	(0.267)	(0.267)	1.770	1.770
TN	1	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)	(1.921)
TX	85	(0.727)	(4.121)	(3.224)	(2.548)	(1.714)	(0.565)	0.303	0.875	1.215	2.576
UT	6	0.244	(1.724)	(1.517)	(1.517)	(0.461)	(0.115)	0.231	1.618	1.618	3.319
VA	5	0.794	(4.066)	(1.925)	0.216	0.860	1.504	1.864	2.223	3.158	4.093
VI	0										
VT	0										
WA	0										
WI	0										
WV	0										
WY	2	(1.247)	(2.474)	(2.474)	(2.474)	(2.474)	(1.247)	(0.020)	(0.020)	(0.020)	(0.020)
All	**443**	**(0.079)**	**(3.677)**	**(2.703)**	**(1.967)**	**(1.141)**	**(0.267)**	**0.635**	**1.413**	**2.621**	**3.975**

Larger-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	12	(0.627)	(3.202)	(2.588)	(2.199)	(1.448)	(1.007)	(0.774)	1.275	1.423	1.897
AL	114	1.632	(1.583)	(0.520)	0.510	1.110	1.856	2.392	3.058	3.833	4.653
AR	90	1.114	(1.830)	(1.158)	(0.185)	0.854	1.403	2.060	2.643	3.090	4.097
AZ	106	0.441	(2.830)	(2.073)	(1.522)	(0.188)	0.547	1.077	1.774	2.880	4.504
CA	991	0.799	(2.856)	(1.930)	(1.130)	(0.306)	0.381	1.528	2.710	4.200	5.000
CO	104	0.059	(3.260)	(2.293)	(1.588)	(0.912)	(0.219)	0.392	1.246	1.946	4.482
CT	74	(0.829)	(3.321)	(2.908)	(2.511)	(1.846)	(1.481)	(0.390)	0.059	1.206	2.448
DC	7	(0.428)	(3.672)	(2.455)	(1.306)	(1.306)	(0.938)	0.289	0.289	0.767	4.319
DE	12	0.141	(2.604)	(1.897)	(1.874)	(1.282)	(0.076)	0.965	1.626	2.274	2.798
FL	676	0.933	(2.436)	(1.416)	(0.655)	0.139	0.760	1.471	2.448	3.530	5.000
GA	99	(0.021)	(2.516)	(1.652)	(1.037)	(0.654)	(0.186)	0.435	0.966	1.653	2.274
GU	3	(1.612)	(1.897)	(1.897)	(1.897)	(1.703)	(1.703)	(1.703)	(1.236)	(1.236)	(1.236)
HI	14	0.760	(2.334)	(2.053)	(0.805)	0.284	1.318	1.711	2.149	2.998	4.064
IA	94	0.344	(2.920)	(2.173)	(1.254)	(0.604)	0.638	1.208	1.865	2.880	3.762
ID	42	0.245	(2.673)	(2.309)	(0.645)	(0.236)	0.028	0.865	1.383	2.297	3.059
IL	398	0.407	(2.854)	(2.065)	(1.441)	(0.656)	(0.008)	0.823	1.873	3.137	5.000
IN	138	(0.149)	(3.068)	(2.166)	(1.455)	(0.890)	(0.452)	0.226	0.991	1.629	3.179
KS	84	0.252	(3.170)	(1.706)	(1.103)	(0.348)	0.131	0.675	1.328	2.425	3.665
KY	90	0.990	(2.331)	(0.892)	(0.404)	0.332	0.781	1.381	2.258	3.365	4.290
LA	167	1.333	(1.902)	(0.762)	0.078	0.597	1.367	2.234	2.865	3.746	4.840
MA	127	(0.162)	(2.991)	(2.207)	(1.508)	(0.943)	(0.091)	0.356	0.752	1.582	2.980
MD	49	0.823	(1.649)	(1.207)	(0.831)	(0.260)	0.298	1.769	2.378	2.867	4.019
ME	19	1.081	(1.718)	(0.501)	0.039	0.505	0.704	0.917	2.069	2.862	4.562
MI	322	0.802	(2.660)	(1.818)	(1.197)	(0.270)	0.657	1.634	2.672	3.671	5.000
MN	97	(0.799)	(3.469)	(2.791)	(2.154)	(1.559)	(1.130)	(0.629)	(0.127)	1.111	2.747
MO	122	0.512	(2.814)	(2.014)	(1.458)	(0.482)	0.222	1.345	2.042	3.280	4.334
MP	1	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)	(0.515)
MS	45	1.325	(1.351)	(0.689)	(0.102)	0.776	1.448	2.121	2.718	3.370	4.414
MT	22	(0.839)	(3.220)	(2.745)	(1.807)	(1.760)	(1.373)	(0.874)	(0.009)	0.957	1.328

TABLE 41: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS (Based on a maximum 5 percent payment adjustment)

			Payment Adjustment Percentile Distribution (%)								
Percentage of Dually-eligible Beneficiaries	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
Low % dually-eligible	2,061	0.464	(2.592)	(1.656)	(0.970)	(0.313)	0.295	0.991	1.658	2.618	3.889
Medium % dually-eligible	4,118	0.153	(2.962)	(2.134)	(1.447)	(0.774)	(0.051)	0.662	1.446	2.425	3.832
High % dually-eligible	1,316	1.066	(3.145)	(1.943)	(1.043)	0.200	1.059	2.226	3.327	4.710	5.000
Acuity (HCC)	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
Low acuity	1,479	1.283	(2.545)	(1.426)	(0.457)	0.435	1.275	2.276	3.265	4.451	5.000
Middle acuity	4,290	0.320	(2.756)	(1.905)	(1.247)	(0.560)	0.187	0.851	1.604	2.601	3.913
High acuity	1,726	(0.162)	(3.283)	(2.446)	(1.753)	(1.143)	(0.460)	0.255	1.081	2.104	3.545
% Rural Beneficiaries	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
All non-rural	3,849	0.483	(2.969)	(2.046)	(1.318)	(0.552)	0.266	1.099	2.020	3.249	5.000
Up to 50% rural	2,265	0.024	(2.873)	(2.089)	(1.438)	(0.822)	(0.140)	0.469	1.200	2.108	3.323
Over 50% rural	1,368	0.783	(2.408)	(1.539)	(0.672)	0.066	0.819	1.390	2.214	3.121	4.414
Organizational Type	**# of HHAs**	**Average Payment Adjustment (%)**	**10%**	**20%**	**30%**	**40%**	**50%**	**60%**	**70%**	**80%**	**90%**
Religious affiliation	289	0.085	(2.658)	(1.807)	(1.294)	(0.794)	(0.252)	0.465	1.123	2.062	3.232
Private not-for-profit	579	(0.010)	(2.961)	(2.053)	(1.432)	(0.891)	(0.262)	0.422	1.098	2.055	3.562
Other not-for-profit	478	0.230	(2.618)	(1.812)	(1.144)	(0.470)	0.160	0.752	1.314	2.296	3.280
Private for-profit	5,869	0.459	(2.913)	(1.997)	(1.271)	(0.500)	0.278	1.044	1.918	3.039	4.677
State	186	0.548	(3.244)	(1.790)	(0.699)	(0.225)	0.441	1.317	2.151	3.047	4.263
Gov't & voluntary	10	1.059	(0.356)	(0.171)	0.073	0.322	0.879	1.395	1.565	1.618	3.134
Local	96	0.583	(2.604)	(1.584)	(0.797)	(0.102)	0.507	1.361	1.834	2.749	3.799

Note: The total number of HHAs differ by category due to missing HHAs in some data sources.

TABLE 42: BURDEN SAVINGS CALCULATIONS

Time Point	Costs with 2020 data	Removal of M2016	Estimate Cost
Transfer of Care	$4,969,755.73	$4,259,790.63	$709,965
Discharge from agency	$230,885,202.34	$228,832,890.59	$2,052,312
TOTAL			**2,762,277** **$242 per HHA (2,762,277/11,400)**

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3. Impacts for the HH QRP for CY 2022

Estimated impacts for the HH QRP are based on analysis discussed in section X.B. of this proposed rule. The proposed HH QRP requirements would reduce burden to the active collection under OMB control number #0938–1279 (CMS–10545; expiration 12/31/21).

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a calendar year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA or that calendar year by 2 percentage points. For the CY 2021, 527 of the 11,196 active Medicare-certified HHAs, or approximately 4.7 percent, did not receive the full annual percentage increase (the methodology accommodated the COVID–19 PHE exception). These 527 HHAs represented $253 million in home health claims payment dollars during the reporting period compared out of a total $16.7B for all HHAs.

As discussed in section IV.C. of this proposed rule, we are proposing to remove one OASIS-based measure beginning with the CY 2023 HH QRP. The assessment-based measure we are proposing to remove is: (1) Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care. We are also proposing to replace the Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171) measure and Emergency Department Use Without Hospitalization During the First 60 Days

of Home Health (NQF #0173) measure with the Home Health Within Stay Potentially Preventable Hospitalization measure beginning with the CY 2023 HH QRP under our measure removal Factor 6: A measure that is more strongly associated with desired patient outcomes for the particular topic is available. Because these three measures are claims-based, there will be no impact to our collection of information.

Section X.B. of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes. The associated burden is for CY 2023 because HHAs will be able to submit data beginning CY 2023. The cost impact related to OASIS item collection as a result of the changes to the HH QRP is estimated to be a net decrease of $2,762,277 in annualized cost to HHAs, discounted at 7 percent relative to year 2020, over a perpetual time horizon beginning in CY 2023.

We describe the estimated burden and cost reductions for these measures in section X.B of this rule.

In summary, the proposed HH QRP measure removals would result in a burden reduction of $242 per HHA annually, or $2,762,277 for all HHAs annually. We have described the burden costs savings in Table 42:

PROHIBITION OF PAYMENT FOR SERVICES OR ITEMS FURNISHED BY DEACTIVATED PROVIDERS AND SUPPLIERS FROM CY 2021 TO 2022	
Providers/Suppliers to Federal Government	$54.1 million

4. Changes to the Home Health CoPs

a. Virtual Supervision of HHA Aides

In section IV.D. of this rule, we propose to revise the CoPs for home health agencies. Specifically, in section IV.D. of this rule, we propose to revise the home health aide supervision requirements to allow for virtual supervision. The burden may be reduced for providers by improving the efficiency of the training and supervision of home health aides. We are also adding the requirement that the skills related to any deficient skills be addressed. We believe the burden associated with addressing skills related to those identified as deficient skills is minimal. Moreover, supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and State and Federal compliance purposes constitutes a usual and customary business practice. Therefore, the regulatory impact is negligible.

b. Permitting Occupational Therapists To Conduct the Initial Assessment Visit and Complete the Comprehensive Assessment for Home Health Agencies Under the Medicare Program

In accordance with Division CC, section 115 of CAA 2021, we are proposing conforming regulations text changes to permit the occupational therapist to complete the initial and comprehensive assessments for Medicare patients when ordered with another rehabilitation therapy service (speech language pathology or physical therapy) that establishes program eligibility, in the case where skilled nursing services are also not ordered. We do not expect any increase in burden for any of these modifications. In fact, for home health agencies, burden may be reduced by expanding the type of therapy discipline able to complete the initial and comprehensive assessments, in some circumstances, for Medicare patients. We do not expect the changes for these provisions will cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

5. Payment for Home Infusion Therapy Services

There are two new proposals in this rule related to payments for home infusion therapy services in CY 2022: The proposal to maintain the CY 2021 percentages for the initial subsequent policy and the proposal to wage adjust HIT service payments using the CY 2022 GAFs Adjustments to the home infusion therapy payment rates will be made when the CY 2022 final GAF values become available and will be budget neutral using the GAF standardization factor. The CY 2021 home infusion therapy service payments will also be updated by the CPI–U reduced by the productivity adjustment. The CY 2022 final GAF values (and the CPI–U as of June 2021) were not available at the time of rulemaking, therefore, we are unable to estimate the impact of these adjustments on the CY 2022 HIT service payment amounts compared to the CY 2021 HIT service payment amounts. We will outline the home infusion therapy payment impacts in the CY 2022 HH PPS final rule.

6. Medicare Provider and Supplier Enrollment Provisions

a. General Impact

Similar to our position regarding information collection requirements, and except as stated in section XI.C.6.b. of this proposed rule, we do not anticipate any costs, savings, or transfers associated with our provider and supplier enrollment proposals. Most of these proposals have been in subregulatory guidance for a number of years, and we are merely incorporating them into regulation; those proposed provisions that are not in subregulatory guidance do not involve any costs, savings, or transfers.

b. Deactivation of Billing Privileges—Payment Prohibition

As explained in section VI.B of this proposed rule, we are proposing in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). Existing subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation of the provider's or supplier's billing privileges. Our proposal would reverse this policy for the reasons stated in section VI.B. of this proposed rule.

Although the figure varies widely by individual provider or supplier, internal CMS data suggests that the average provider/supplier impacted by this proposal receives roughly $50,000 in Medicare payments each year. (We used a similar $50,000 annual payment estimate for our provider enrollment provisions in a CMS final rule published in the **Federal Register** on November 15, 2019 titled, ''CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies'') (84 FR 62568). As with annual payment amounts, the number of deactivations vary per year. Nonetheless, and based on internal CMS data, we estimate 13,000 deactivations annually. This results in an approximate burden of $54,145,000 per year ($13,000 \times 50,000 \times 0.0833$). (The 0.0833 figure represents

30 days, or 1/12 of a year.) The following table reflects the estimated transfers associated with our proposed addition of new § 424.540(e) concerning payments for services and items furnished by deactivated providers and suppliers:

PROHIBITION OF PAYMENT FOR SERVICES OR ITEMS FURNISHED BY DEACTIVATED PROVIDERS AND SUPPLIERS FROM CY 2021 TO 2022	
Providers/Suppliers to Federal Government	$54.1 million

7. Survey and Enforcement Requirements for Hospice Providers

Estimated impacts for the Survey and Certification Requirements for Hospice Program Providers are based on analysis discussed in section VII. of this proposed rule.

a. Application and Re-Application Procedures for National Accrediting Organizations (§ 488.5)

We proposed at § 488.5(a)(4)(x) to require AOs with CMS-approved hospice programs to include a statement of deficiencies, (that is, the Form CMS–2567 or a successor form) to document survey findings of the hospice Medicare CoPs and to submit such in a manner specified by CMS. This implements new section 1822(a)(2)(A)(ii) of the Act. We anticipate effects on AO administrative expenses but are not able to provide an accurate estimate of how much cost and time will result from including the Form CMS–2567 into their proprietary IT systems and subsequently submitting the information to CMS. Currently, there are three AOs with CMS-approved hospice programs affected by this proposal. We seek comments that would help us to develop an accurate estimate of the cost and time burden that would result from this collection of information.

b. Release and Use of Accreditation Surveys (§ 488.7)

CAA 2021 adds section 1822(a)(2)(B) of the Act which requires that CMS publish hospice survey information from the Form CMS–2567 in a way that is readily understandable and useable by the public in a meaningful way. We anticipate the need for CMS to develop some type of a standard framework that would identify salient survey findings in addition to other relevant data about the hospices' performance. CMS recognizes that the implications of releasing national survey data will require collaboration with industry stakeholders to assure the development is fair and equitable across all hospice programs.

c. Hospice Hotline (§ 488.1110)

Section 1864(a) of the Act was amended by inserting ''hospice programs'' after information on the home health toll-free hotline. The infrastructure for a State or local agency toll-free hotline is already in place for HHAs to collect and maintain complaint information related to HHAs. The requirement allows the existing hotline to collect complaint information on hospices. We do not expect the changes for this provision will cause any appreciable amount of expense or anticipated saving and we do not believe this standard would impose any additional regulatory burden.

d. Surveyor Qualifications and Prohibition of Conflicts of Interest (§ 488.1115)

We propose at § 488.1115, to require AO hospice program surveyors to complete the CMS hospice basic training currently available online. The hospice basic training course has an average completion time of 24 hours. Completion time could be more or less depending upon the learner's familiarity with the content and overall learning style. We are not able to estimate precisely total time and cost burden to each AO for the wages incurred for the time spent by all surveyors from each of the three hospice program AOs to take the CMS online surveyor training course, because each AO varies greatly in organization size, number of accreditation programs approved by CMS, and total surveyor cadre numbers. There are no regulatory requirements for AOs to report to CMS on the number of surveyors within their organization nor information on how many of those surveyors survey each type of program approved by CMS. CMS notes there is a wide variety of total surveyor cadre numbers across all three AOs, based on information CMS has gathered from confidential numbers, voluntarily provided by some of the AOs to CMS, as part of their deeming authority application documents as well as information found online via a search of each AOs public website. Variation is generally based on the associated number of CMS-approved accreditation programs the AO possesses. For example, AOs who accredit only one provider or supplier type generally have about 25 surveyors while AOs with multiple programs have surveyor numbers well over 300 thereby skewing the ability to estimate an accurate time burden that represents the overall group. Because of this wide range CMS is estimating near the middle, using the range of 100 total surveyors per AO. If we estimate that each AO has approximately 100 total surveyors, the estimated time burden to each AO associated with this requirement would be 2,400 hours (24 hours × 100 surveyors).

The estimated cost burden to each AO with CMS-approved hospice programs associated with this requirement would be $184,656 (2,400 hours × $76.94 per hour (based on the salary of a registered nurse. See Table 37)).

As of March 2021, there are three AOs that accredit Medicare-certified hospice programs. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 7,200 hours (2,400 hours × 3 AOs). The estimated cost across all AOs (that accredit Medicare-certified hospice programs) would be $553,968 ($184,656 × 3 AOs). We also proposed to set out the circumstances that will disqualify a surveyor from surveying a particular hospice in accordance with new section 1822(a)(4)(B) of the Act). We do not expect these proposed changes will cause any appreciable amount of expense or anticipated saving because the provisions codify longstanding policies and basic principles to ensure there is no conflict of interest between organizations and surveyors.

e. Survey Teams (§ 488.1120)

We propose at § 488.1120 that when the survey team comprises more than one surveyor, the additional slots would be filled by multidisciplinary professionals such as physicians, nurses, medical social workers, pastoral or other counselors—bereavement, nutritional, and spiritual. At this time, we do not have specific information related to current survey team compositions but we do know there are approximately 977 hospice surveys per year, with at least one member of the survey team being a registered nurse.

The proposed inclusion of multidisciplinary survey team members could potentially increase the overall cost of surveys if SA and AOs were not already using a mixed team.

The 2020 Bureau of Labor Statistics estimates RN adjusted hourly wages at $76.94 (including fringe benefits and overhead). Other potential disciplines fall below and above the RN adjusted hourly wage, for example: Social workers—$50.12 per hour, pharmacists—$120.64 per hour, and psychologists—$108.36 per hour. A survey team of all nurses (assuming a two-person team) costs $153.88 ($76.94 × 2) per hour. However, CMS believes the most common multidisciplinary team for hospice program surveys may include a nurse and a social worker. Using this assumption, we calculate it will cost $127.06 ($76.94 + $50.12) per hour for this multidisciplinary 2-person survey team composition. Therefore, a two-person multidisciplinary team at $127.06 per hour, assuming a 5-day survey (8 hours per day × 5 days = 40 hours), would cost $5,082.40 per survey, times 960 surveys per year, or $4,879,104 per year. We seek comments on the current professional makeup of the AO and SA survey teams, and providers' estimates of the time needed to effectuate multidisciplinary teams where they do not currently exist.

f. Consistency of Survey Results (§ 488.1125)

Actions to improve consistency of survey results are discussed elsewhere in terms of implementing the use of the Form CMS–2567 across surveying entities and utilizing a common training platform. We do not anticipate additional costs or burdens to surveying entities. Some cost will be incurred by CMS to develop the system (technical and personnel) to analyze and apply correction where needed.

g. Special Focus Program (§ 488.1130)

There may be an additional SA burden in terms of the need for enhanced survey and enforcement activities which is in part why a more methodical and targeted approach to the implementation of this program should be considered given the allocation of $10 million to support this and the other provisions that would not begin until FY 2022.

h. Enforcement Remedies (§§ 488.1200 Through § 488.1265)

We propose enforcement remedies for hospices consistent with the established alternative sanctions for HHAs. In CY 2019, out of 11,738 deemed and non-deemed HHAs enrolled in the Medicare program, 749 HHA providers had the potential to be sanctioned based on repeat deficiencies during two consecutive standard or complaint surveys. This was approximately 15 percent of the HHAs, which is less than 37.5 percent of the total HHAs surveyed. Of all the alternative sanctions available for implementation, very few HHA enforcement actions were imposed. In CY 2019, less than 10 percent of all HHAs with surveys identifying an immediate jeopardy level deficiency citation received an alternative sanction.

The probability of impact for alternative enforcement remedies imposed against hospices is based on CY 2019 data for 5,065 deemed and non-deemed hospices enrolled in the Medicare program. This data was examined using the survey data for the CY 2019 in the *CMS QCOR system.* Of the total number of CMS-certified hospices, 4,399 received an unannounced standard and/or complaint survey and 236 were cited for noncompliance with one or more condition-level deficiencies. Therefore, approximately 5 percent of the total hospices surveyed had the potential to receive an enforcement remedy based on noncompliance with one or more CoPs.

The enforcement remedy provisions in this proposed rule mirror the alternative sanctions used in HHAs that have already been incorporated into CMS policy. Therefore, in terms of the administrative expenses to design and manage these types of remedies, the infrastructure is already in place. In terms of training for Federal and State surveyors, it is common for surveyors that survey HHAs to be cross-trained to survey hospices. Since the enforcement remedies for hospice are similar to those for HHAs, we expect that there will be a minimal burden on seasoned surveyors to become familiar with these provisions. Additionally, the data analysis described previously for hospices in CY 2019 reflects the probability of a low impact for civil monetary penalties to be imposed on hospice providers.

8. Certain Compliance Date Changes for the IRF QRP and LTCH QRP

a. Impacts for the Inpatient Rehabilitation Facility Quality Reporting Program for FY 2023

This proposed rule would 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 this information collection, which have already received OMB approval.

In accordance with section 1886(j)(7)(A) of the Act, the Secretary must reduce by 2 percentage points the annual market basket increase factor otherwise applicable to an IRF for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. As stated in section VIII.A. of this proposed rule for purposes of calculating the FY 2023 Annual Increase Factor (AIF), we propose that IRFs would begin using the IRF–PAI V4.0 to collect data on the TOH Information to Provider-PAC and the TOH Information to Patient-PAC measures beginning with admissions and discharges on October 1, 2022. We also proposed that IRFs would begin to use the IRF–PAI V4.0 to collect data on certain Standardized Patient Assessment Data Elements, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

The proposed IRF QRP requirements would add no additional burden or cost to the active collection under OMB control number 0938–0842 (expiration 12/31/2022).

b. Impacts for the Long-Term Care Hospital Quality Reporting Program for FY 2023

This proposed rule 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 this information collection discussed later in this section, which have already received OMB approval.

In accordance with section 1886(m)(5) of the Act, the Secretary must reduce by 2 percentage points the annual market basket payment update otherwise applicable to a LTCH for a fiscal year if the LTCH does not comply with the requirements of the LTCH QRP for that fiscal year. As stated in section VIII.B. of this proposed rule for purposes of calculating the FY 2023 Annual Payment Update (APU), we propose that LTCHs would begin using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) V5.0 to collect data on the TOH Information to Provider-PAC and the TOH Information to Patient-PAC measures beginning with admissions and discharges on October 1, 2022. We also

proposed that LTCHs would begin to use the LTCH LCDS V5.0 to collect data on certain Standardized Patient Assessment Data Elements, beginning with admissions and discharges (except for the hearing, vision, race, and ethnicity Standardized Patient Assessment Data Elements, which would be collected at admission only) on October 1, 2022.

The proposed LTCH QRP requirements would add no additional burden or cost to the active collection under OMB control number 0938–1163 (expiration 12/31/2022).

D. Limitations of Our Analysis

Our estimates of the effects of this proposed rule are subject to significant uncertainty. It is difficult to estimate the burden and savings from the proposed changes because they depend on several factors previously described. We appreciate that our assumptions are simplified and that actual results could be considerably higher or lower. Although there is uncertainty concerning the magnitude of all of our estimates, we do not have the data to provide specific estimates for each proposal, as to the range of possibilities, or to estimate all categories of possible benefits. We seek comments on all aspects of this analysis.

E. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique reviewers of this year's proposed rule would be the similar to the number of commenters on last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which would review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $114.24 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* This proposed rule consists of approximately 121,000 words. Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 4.03 hours for the staff to review half of this rule. For each entity that reviews the rule (we estimate that there are 165 reviewers), the estimated cost is $574 (4.03 hours × $114.24). Therefore, we estimate that the total cost of reviewing this proposed rule is $75,964.35 ($460.39 × 165 reviewers).

F. Alternatives Considered

1. Alternatives Considered to the HH PPS Policy Proposals

For the CY 2022 HH PPS proposed rule, we considered alternatives to the proposals articulated in section II. of this proposed rule. We considered using CY 2019 data for ratesetting. However, our analysis showed there were only small differences in the payment rates and impacts in the aggregate when using CY 2019 data compared to CY 2020 data. These differences in payment rates reflect small differences in the wage index budget neutrality factors calculated using CY 2020 data compared to using CY 2019 claims data. We note, we would not have recalibrated the case-mix weights using CY 2019 data because CY 2019 data would use simulated 30-day periods from 60-episodes as CY 2020 is the first year of actual PDGM data. Therefore, no case-mix weight budget neutrality factor using CY 2019 utilization data would be applied. We believe it is best to continue with our established policy of using the most recent, complete data at the time of rulemaking for CY 2022 ratesetting, which would be CY 2020 claims data. Additionally, we considered alternatives to our case-mix recalibration proposal. These alternatives included an option do a full recalibration of the case-mix weights, including the functional impairment levels, comorbidity subgroups as proposed, but also updating the LUPA thresholds, as well as an option to not recalibrate the case-mix weights, functional impairment levels, comorbidity subgroups and LUPA thresholds. However, we believe that recalibrating the PDGM case-mix weights, functional levels, and comorbidity adjustment subgroups while maintaining the LUPA thresholds for CY 2022 would more accurately adjust home health payments because the data would reflect 30-day periods under the new PDGM system based on actual data rather than data that simulated 30-day episodes under the old system. The recalibrated case-mix weights would also more accurately reflect the types of patients currently receiving home health services while mitigating instability by maintaining the LUPA thresholds. As stated previously the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (as is used to generate the case-mix weight) that would control for the impacts of the PHE. We note that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Also, our analysis shows that there is more variation in the case-mix weights with the full recalibration (including updates to the LUPA thresholds) than the recalibration with the case-mix weights maintained. Maintaining the LUPA thresholds creates more stability in the weights. The recalibrated case-mix weights using the current LUPA thresholds are more similar to the CY 2020 weights than the recalibrated case-mix weights with the updated LUPA thresholds. For these reasons, we believe it is best to maintain the LUPA thresholds for CY 2022 instead of the alternative full recalibration including updates to the LUPA thresholds.

2. Alternatives Considered to the HHVBP Policy Proposals

We considered alternatives to the proposed policies in sections III.A. and III.B. of this proposed rule. Specifically, we considered not expanding the HHVBP Model at this point in time, and waiting until we have final evaluation results from the original HHVBP Model before pursuing a national expansion. However, we considered that we have evaluation results from multiple years of the original HHVBP Model, showing significant reductions in spending and improvements in quality. We believe this evidence is sufficient for a national expansion of the Model, and note that we will continue to review evaluation results as they come in for the later years of the original HHVBP Model.

For the expanded HHVBP Model, we also considered utilizing the same state- and volume-based cohorts as the original HHVBP Model in lieu of the national volume-based cohorts we are proposing. However, this approach

could require grouping together of certain States, territories, and the District of Columbia that have an insufficient number of HHAs at the end of the performance year, based solely on their lower HHA counts. This would also preclude providing benchmarks and achievement thresholds prospectively. An analysis of the State-level impacts of using the revised cohorts, including our proposed option, nationwide with volume-based cohorts, and our alternative, State-level without volume-based cohorts, demonstrates minimal impacts at the State-level. Using CY 2019 data to simulate the payment adjustments, the mean payment adjustments at the State-level are within +/− 1.0 percent for both cohort options. Relative to the State- and volume-based cohorts, the national volume-based cohorts resulted in the largest increases in overall payment amounts to Alabama (+1.8 percent), Mississippi (+1.8 percent), and TN (+1.4 percent). The largest decreases in overall payment amounts are from Minnesota (−1.7 percent), Connecticut (−1.6 percent), and the Marianas Islands (−1.6 percent). We do not see any obvious correlation of the impacts within States that are currently in the original Model versus those that will be new to the expanded Model.

For the reasons described in section III.B.2. of this proposed rule, we are proposing to not apply any payment adjustments for CY 2022 of the original HHVBP Model based on data reported in CY 2020 and to instead end the original Model early, with the CY 2021 payment adjustment year. As previously noted, we will continue to examine data for CY 2020 as it becomes available in order to determine whether it would be appropriate to utilize such data for CY 2022 payment adjustments, in accordance with current Model policies.

3. Alternatives Considered Concerning Deactivation Payment Prohibition

As discussed in section VI.B. of this proposed rule, we are proposing in new § 424.540(e) that a provider or supplier may not receive payment for services or items furnished while deactivated under § 424.540(a). Current subregulatory guidance permits the provider or supplier to bill for services or items furnished up to 30 days prior to the effective date of the reactivation of the provider's or supplier's billing privileges. We considered the alternative of retaining this 30-day retroactive period. After careful consideration, however, we concluded that prohibiting such retroactive payments would be the best approach from a program integrity perspective. As we stated in section VI.B. of this proposed rule, we do not believe a provider or supplier should be effectively rewarded for its non-adherence to enrollment requirements by receiving retroactive payment for services or items furnished while out of compliance. Moreover, the prospect of a payment prohibition could well spur providers and suppliers to avoid such non-compliance.

G. Accounting Statement and Tables

1. HH PPS

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 43, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2022 HH PPS provisions of this rule.

TABLE 43: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2021 TO 2022

Category	Transfers
Annualized Monetized Transfers	$310 million
From Whom to Whom?	Federal Government to HHAs

2. HHVBP Model Expansion

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 44, we have prepared an accounting statement showing the classification of the expenditures associated with this proposed rule as they relate to hospitals and SNFs. Table 44 provides our best estimate of the decrease in Medicare payments under the proposed expanded HHVBP Model.

TABLE 44: ACCOUNTING STATEMENT: EXPANDED HHVBP MODEL CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS FOR CYs 2022 – 2026

Category	Transfers	Discount Rate	Period Covered
Annualized Monetized Transfers	-$769.2 Million	7%	CYs 2022-2026
Annualized Monetized Transfers	-$688.7 Million	3%	CYs 2022-2026
From Whom to Whom?	Federal Government to Hospitals and SNFs		

3. HHQRP

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), in Table 45, we have prepared an accounting statement showing the classification of the expenditures associated with this proposed rule as they relate to HHAs. Table 45 provides our best estimate of the decrease in Medicare payments.

TABLE 45: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2021 TO CY 2022

Category	Costs
Annualized Net Decreased Monetary Burden for HHAs' Submission of the OASIS	$-2,762,277

H. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. In addition, HHAs and home infusion therapy suppliers are small entities, as that is the term used in the RFA. Individuals and States are not included in the definition of a small entity.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title ''Home Health Care Services'' and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of $16.5 million [143] and approximately 96 percent of HHAs and home infusion therapy suppliers are considered small entities. Table 46 shows the number of firms, revenue, and estimated impact per home health care service category.

TABLE 46: NUMBER OF FIRMS, REVENUE, AND ESTIMATED IMPACT OF HOME HEALTH CARE SERVICES BY NAICS CODE 621610

NAICS Code	NAICS Description	Enterprise Size	Number of Firms	Receipts ($1,000)	Estimated Impact ($1,000) per Enterprise Size
621610	Home Health Care Services	<100	5,861	210,697	$35.95
621610	Home Health Care Services	100-499	5,687	1,504,668	$264.58
621610	Home Health Care Services	500-999	3,342	2,430,807	$727.35
621610	Home Health Care Services	1,000-2,499	4,434	7,040,174	$1,587.77
621610	Home Health Care Services	2,500-4,999	1,951	6,657,387	$3,412.29
621610	Home Health Care Services	5,000-7,499	672	3,912,082	$5,821.55
621610	Home Health Care Services	7,500-9,999	356	2,910,943	$8,176.81
621610	Home Health Care Services	10,000-14,999	346	3,767,710	$10,889.34
621610	Home Health Care Services	15,000-19,999	191	2,750,180	$14,398.85
621610	Home Health Care Services	≥20,000	961	51,776,636	$53,877.87
621610	Home Health Care Services	Total	23,801	82,961,284	$3,485.62

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2017" (SOURCE: 2017 County Business Patterns and Economic Census) Release Date: 5/28/2021: https://www2.census.gov/programs-surveys/susb/tables/2017/

Notes: Estimated impact is calculated as Receipts ($1,000)/Enterprise Size.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would not result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. We note also, and as discussed in section XI.C.6. of this proposed rule, our proposal to prohibit payments for services and items furnished by deactivated providers and suppliers would affect only a very limited number of Medicare providers and suppliers. Therefore, the Secretary has determined that this HH PPS proposed rule would not have significant economic impact on a substantial number of small entities.

Guidance issued by the Department of Health and Human Services interpreting the Regulatory Flexibility Act considers the effects economically 'significant' only if greater than 5 percent of providers reach a threshold of 3- to 5-percent or more of total revenue or total costs. Among the over 7,500 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this rule would be larger than 3 percent, in magnitude, for about 28 percent of competing HHAs (estimated by applying the proposed 5-percent maximum payment adjustment under the expanded Model to CY 2019 data). As a result, more than the RFA threshold of 5-percent of HHA providers nationally would be significantly impacted. We refer readers to Tables G6 and G7 of this proposed rule for our analysis of

[143] *https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%2019%2C%202019_Rev.pdf.*

payment adjustment distributions by State, HHA characteristics, HHA size and percentiles.

Thus, the Secretary has determined that this proposed rule would have a significant economic impact on a substantial number of small entities. Though the RFA requires consideration of alternatives to avoid economic impacts on small entities, the intent of the rule, itself, is to encourage quality improvement by HHAs through the use of economic incentives. As a result, alternatives to mitigate the payment reductions would be contrary to the intent of the rule, which is to test the effect on quality and costs of care of applying payment adjustments based on HHAs' performance on quality measures.

I. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA of 1995 UMRA 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 is approximately $158 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $158 million or more.

J. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on State or local governments.

K. Conclusion

In conclusion, we estimate that the provisions in this proposed rule would result in an estimated net increase in home health payments of 1.7 percent for CY 2022 ($310 million). The $310 million increase in estimated payments for CY 2022 reflects the effects of the CY 2022 home health payment update percentage of 1.8 percent ($330 million increase) and an estimated 0.1 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2022 ($20 million decrease).

L. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this proposed rule.

I, Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 16, 2021.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical centers, Health facilities, Health professions, Medicare, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 409—HOSPITAL INSURANCE BENEFITS

■ 1. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 409.43 is amended—
■ a. By revising the paragraph (b) subject heading;
■ b. In paragraph (c)(1)(i)(C) by removing the phrase ''physician's orders'' and adding in its place the phrase ''physician's or allowed practitioner's orders'';
■ c. In paragraphs (c)(1)(i)(D), (c)(2)(i), and (c)(3) by removing the term ''physician'' and adding in its place the phrase ''physician or allowed practitioner''; and
■ d. In paragraph (d) by removing the phrase '' based on a physician's oral orders'' and adding in its place the phrase ''based on a physician's or allowed practitioner's oral orders''.

The revision reads as follows:

§ 409.43 Plan of care requirements.

* * * * *

(b) *Physician's or allowed practitioner's orders.* * * *

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 3. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 4. Section 424.520 is amended by revising paragraph (d) to read as follows:

§ 424.520 Effective date of billing privileges.

* * * * *

(d) *Additional provider and supplier types.* (1) The effective date of billing privileges for the provider and supplier types identified in paragraph (d)(2) of this section is the later of—

(i) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or

(ii) The date that the provider or supplier first began furnishing services at a new practice location.

(2) The provider and supplier types to which paragraph (d)(1) of this section applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

■ 5. Section 424.521 is amended by revising the section heading and paragraph (a) to read as follows:

§ 424.521 Request for payment by certain provider and supplier types.

(a) *Request for payment by certain provider and supplier types.* (1) The providers and suppliers identified in paragraph (a)(2) of this section may retrospectively bill for services when

the provider or supplier has met all program requirements (including State licensure requirements), and services were provided at the enrolled practice location for up to—

(i) Thirty days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or

(ii) Ninety days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121–5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

(2) The provider and supplier types to which paragraph (a) applies are as follows:

(i) Physicians.

(ii) Non-physician practitioners.

(iii) Physician organizations.

(iv) Non-physician practitioner organizations.

(v) Ambulance suppliers.

(vi) Opioid treatment programs.

(vii) Part B hospital departments.

(viii) Clinical Laboratory Improvement Amendment labs.

(ix) Intensive cardiac rehabilitation facilities.

(x) Mammography centers.

(xi) Mass immunizers/pharmacies.

(xii) Radiation therapy centers.

(xiii) Home infusion therapy suppliers.

(xiv) Physical therapists.

(xv) Occupational therapists.

(xvi) Speech language pathologists.

* * * * *

■ 6. Section 424.522 is added to read as follows:

§ 424.522 Additional effective dates.

(a) *Reassignments.* A reassignment of benefits under § 424.80 is effective beginning 30 days before the Form CMS–855R is submitted if all applicable requirements during that period were otherwise met.

(b) *Form CMS–855O enrollment.* The effective date of a Form CMS–855O enrollment is the date on which the Medicare contractor received the Form CMS–855O application if all other requirements are met.

■ 7. Section 424.525 is amended—

■ a. By revising paragraph (a)(1);

■ b. In paragraphs (a)(2), (a)(3), and (b) by removing the phrase ''prospective provider'' and adding the word ''provider'' each time it appears; and

■ c. By adding paragraph (e).

The revision and addition read as follows:

§ 424.525 Rejection of a provider's or supplier's application for Medicare enrollment.

(a) * * *

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the Medicare contractor's request for the missing information. This includes the following situations:

(i) The application is missing data required by CMS or the Medicare contractor to process the application (such as, but not limited to, names, Social Security Number, contact information, and practice location information).

(ii) The application is unsigned or undated.

(iii) The application contains a copied or stamped signature.

(iv) The application is signed more than 120 days prior to the date on which the Medicare contractor received the application.

(v) The application is signed by a person unauthorized to do so under this subpart.

(vi) For paper applications, the required certification statement is missing.

(vii) The paper application is completed in pencil.

(viii) The application is submitted via fax or email when the provider or supplier was not otherwise permitted to do so.

(ix) The provider or supplier failed to submit all of the forms needed to process a Form CMS–855 reassignment package within 30 days of receipt.

(x) The provider or supplier submitted the incorrect Form CMS–855 application.

* * * * *

(e) *Applicability.* Except as otherwise specified in the applicable reason for rejection under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions, including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 (Electronic Funds Transfer (EFT) Authorization Agreement) submissions.

(3) Form CMS–20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (e)(1) through (3) of this section.

■ 8. Section 424.526 is added to read as follows:

§ 424.526 Return of a provider's or supplier's enrollment application.

(a) *Reasons for return.* CMS may return a provider's or supplier's enrollment application for any of the following reasons:

(1) The provider or supplier sent its paper Form CMS–855, Form CMS–588, or Form CMS–20134 application to the incorrect Medicare contractor for processing.

(2) The Medicare contractor received the application more than 60 days prior to the effective date listed on the application. (This does not apply to providers and suppliers submitting a Form CMS–855A application, ambulatory surgical centers, or portable x-ray suppliers.)

(3) The seller or buyer in a change of ownership submitted its Form CMS–855A or Form CMS–855B application more than 90 days prior to the anticipated date of the sale.

(4) The Medicare contractor received an initial application more than 180 days prior to the effective date listed on the application from a provider or supplier submitting a Form CMS–855A application, an ambulatory surgical center, or a portable x-ray supplier.

(5) The Medicare contractor confirms that the provider or supplier submitted an initial enrollment application prior to the expiration of the time period in which it is entitled to appeal the denial of its previously submitted application.

(6) The provider or supplier submitted an initial enrollment application prior to the expiration of their existing re-enrollment bar under § 424.535 or reapplication bar under § 424.530(f).

(7) The application is not needed for (or is inapplicable to) the transaction in question.

(8) The provider or supplier submitted a revalidation application more than 7 months prior to the provider's or supplier's revalidation due date.

(9) A Medicare Diabetes Prevention Program supplier submitted an application with a coach start date more than 30 days in the future.

(10) The provider or supplier requests that their application be withdrawn prior to or during the Medicare contractor's processing thereof.

(11) The provider or supplier submits an application that is an exact duplicate of an application that has already been processed or is currently being processed or is pending processing.

(12) The provider or supplier submits a paper Form CMS–855 or Form CMS–20134 enrollment application that is outdated or has been superseded by a revised version.

(13) The provider or supplier submits a Form CMS–855A or Form CMS–855B initial application followed by a Form CMS–855A or Form CMS–855B change of ownership application. If the Medicare contractor—

(i) Has not yet made a recommendation for approval concerning the initial application, both applications may be returned.

(ii) Has made a recommendation for approval concerning the initial application, the Medicare contractor may return the change of ownership application. If, per the Medicare contractor's written request, the provider or supplier fails to submit a new initial Form CMS–855A or Form CMS–855B application containing the new owner's information within 30 days of the date of the letter, the Medicare contractor may return the originally submitted initial Form CMS–855A or Form CMS–855B application.

(b) *Appeals.* A provider or supplier is not afforded appeal rights if their application is returned under this section.

(c) *Applicability.* Except as otherwise specified in the applicable return reason under paragraph (a) of this section, this section applies to all CMS Medicare provider enrollment application submissions including, but not limited to, the following:

(1) Form CMS–855 initial applications, change of information requests, changes of ownership, revalidations, and reactivations.

(2) Form CMS–588 submissions.

(3) Form CMS–20134 submissions.

(4) Any electronic or successor versions of the forms identified in paragraphs (c)(1) through (3) of this section.

■ 9. Section 424.540 is amended—

■ a. By revising paragraph (a)(2);

■ b. By adding paragraphs (a)(4) through (8);

■ c. By revising paragraphs (b)(1) and (c); and

■ d. By adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 424.540 Deactivation of Medicare billing privileges.

(a) * * *

(2) The provider or supplier does not report a change to the information supplied on the enrollment application within the applicable time period required under this title.

* * * * *

(4) The provider or supplier is not in compliance with all enrollment requirements in this title.

(5) The provider's or supplier's practice location is non-operational or otherwise invalid.

(6) The provider or supplier is deceased.

(7) The provider or supplier is voluntarily withdrawing from Medicare.

(8) The provider is the seller in an HHA change of ownership under § 424.550(b)(1).

(b) * * *

(1) In order for a deactivated provider or supplier to reactivate its Medicare billing privileges, the provider or supplier must recertify that its enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

* * * * *

(c) *Effect of deactivation.* The deactivation of Medicare billing privileges does not have any effect on a provider's or supplier's participation agreement or any conditions of participation.

(d) *Effective dates.* (1)(i) Except as provided in paragraph (d)(1)(ii) of this section, the effective date of a deactivation is the date on which the deactivation is imposed under this section.

(ii) A retroactive deactivation effective date (based on the date that the provider's or supplier's action or non-compliance occurred or commenced (as applicable)) may be imposed in the following instances:

(A) For the deactivation reasons in paragraphs (a)(2) through (4) of this section, the effective date is the date on which the provider or supplier became non-compliant.

(B) For the deactivation reason in paragraph (a)(5) of this section, the effective date is the date on which the provider's or supplier's practice location became non-operational or otherwise invalid.

(C) For the deactivation reason in paragraph (a)(6) of this section, the effective date is the date of death of the provider or supplier.

(D) For the deactivation reason in paragraph (a)(7) of this section, the effective date is the date on which the provider or supplier voluntarily withdrew from Medicare.

(E) For the deactivation reason in paragraph (a)(8) of this section, the effective date is the date of the sale.

(2) The effective date of a reactivation of billing privileges under this section is the date on which the Medicare contractor received the provider's or supplier's reactivation submission that was processed to approval by the Medicare contractor.

(e) *Payment prohibition.* A provider or supplier may not receive payment for services or items furnished while deactivated under this section.

■ 10. Section 424.550 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 424.550 Prohibitions on the sale or transfer of billing privileges.

* * * * *

(b) * * *

(2)(i) The HHA submitted two consecutive years of full cost reports since initial enrollment or the last change in majority ownership, whichever is later. For purposes of this exception, low utilization or no utilization cost reports do not qualify as full cost reports.

* * * * *

PART 484—HOME HEALTH SERVICES

■ 11. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 12. Section 484.55 is amended by revising paragraphs (a)(2) and (b)(3) to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(a) * * *

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician or allowed practitioner who is responsible for the home health plan of care, the initial assessment visit may be made by the appropriate rehabilitation skilled professional. For Medicare patients, an occupational therapist may complete the initial assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

(b) * * *

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician or allowed practitioner, a physical therapist, speech-language pathologist, or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. For Medicare patients, the occupational therapist may complete the comprehensive assessment when occupational therapy is ordered with another qualifying rehabilitation therapy service (speech-language pathology or physical therapy) that establishes program eligibility.

* * * * *

■ 13. Section 484.80 is amended by
■ a. Revising paragraph (h)(1)(i);
■ b. Redesignating paragraphs (h)(1)(ii) and (iii) as (h)(1)(iii) and (iv), respectively;
■ c. Adding a new paragraph (h)(1)(ii); and
■ d. Revising paragraphs (h)(2) and (3).

The revisions and addition read as follows:

§ 484.80 Condition of participation: Home health aide services.

* * * * *

(h) * * *

(1)(i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech language pathology services—

(A) A registered nurse or other appropriate skilled professional who is familiar with the patient, the patient's plan of care, and the written patient care instructions described in paragraph (g) of this section, must complete a supervisory assessment of the aide services being provided no less frequently than every 14 days; and

(B) The home health aide does not need to be present during the supervisory assessment described in paragraph (h)(1)(i)(A) of this section.

(ii) The supervisory assessment must be completed onsite (that is, an in person visit), or by using two-way audio-video telecommunications technology that allows for real-time interaction between the registered nurse (or other appropriate skilled professional) and the patient, not to exceed 2 virtual supervisory assessments per HHA in a 60-day period.

* * * * *

(2)(i) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech language pathology services—

(A) The registered nurse must make an onsite, in person visit every 60 days to assess the quality of care and services provided by the home health aide and to ensure that services meet the patient's needs; and

(B) The home health aide does not need to be present during this visit.

(ii) Semi-annually the registered nurse must make an on-site visit to the location where a patient is receiving care in order to observe and assess each home health aide while he or she is performing non-skilled care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and the home health aide must complete, retraining and a competency evaluation for the deficient and all related skills.

* * * * *

Subpart F—Home Health Value-Based Purchasing (HHVBP) Models

■ 14. The heading for subpart F is revised to read as set forth above.
■ 15. Subpart F is amended by adding an undesignated center heading before § 484.300 to read as follows:

HHVBP Model Components for Competing Home Health Agencies Within State Boundaries for the Original HHVBP Model

■ 16. Section 484.305 is amended by revising the definition of ''Applicable percent'' to read as follows:

§ 484.305 Definitions.

* * * * *

Applicable percent means a maximum upward or downward adjustment for a given performance year, not to exceed the following:

(1) For CY 2018, 3-percent.
(2) For CY 2019, 5-percent.
(3) For CY 2020, 6-percent.
(4) For CY 2021, 7-percent.

* * * * *

§ 484.315 [Amended]

■ 17. Section 484.315 is amended by removing paragraph (d).
■ 18. Subpart F is amended by adding an undesignated center heading and §§ 484.340 through 484.375 to read as follows:

* * * * *

HHVBP Model Components for Competing Home Health Agencies (HHAs) for HHVBP Model Expansion—Effective January 1, 2022

Sec.

484.340 Basis and scope of subpart.
484.345 Definitions.
484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.360 Calculation of the Total Performance Score.
484.365 Payments for home health services under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.
484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

HHVBP Model Components for Competing Home Health Agencies (HHAs) for HHVBP Model Expansion—Effective January 1, 2022

§ 484.340 Basis and scope of subpart.

This subpart is established under sections 1102, 1115A, and 1871 of the Act (42 U.S.C. 1315a), which authorizes the Secretary to issue regulations to operate the Medicare program and test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals under Titles XVIII and XIX.

§ 484.345 Definitions.

As used in this subpart—

Achievement threshold means the median (50th percentile) of home health agency performance on a measure during a baseline year, calculated separately for the larger- and smaller-volume cohorts.

Applicable measure means a measure (OASIS- and claims-based measures) or a measure component (HHCAHPS survey measure) for which a competing HHA has provided a minimum of one of the following:

(1) Twenty home health episodes of care per year for each of the OASIS-based measures.

(2) Twenty home health episodes of care per year for each of the claims-based measures.

(3) Forty completed surveys for each component included in the HHCAHPS Survey measure.

Applicable percent means a maximum upward or downward adjustment for a given payment year based on the applicable performance year, not to exceed 5 percent.

Baseline year means the year against which measure performance in a performance year will be compared.

Benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline year, calculated separately for the larger- and smaller-volume cohorts.

Competing home health agency or agencies (HHA or HHAs) means an agency or agencies that meet the following:

(1) Has or have a current Medicare certification; and

(2) Is or are being paid by CMS for home health care services.

Home health prospective payment system (HH PPS) refers to the basis of payment for HHAs as set forth in §§ 484.200 through 484.245.

Improvement threshold means an individual competing HHA's

performance level on a measure during the baseline year.

Larger-volume cohort means the group of competing HHAs that are participating in the HHCAHPS survey in accordance with § 484.245.

Linear exchange function is the means to translate a competing HHA's Total Performance Score into a value-based payment adjustment percentage.

Nationwide means the 50 States and the US territories, including the District of Columbia.

Payment adjustment means the amount by which a competing HHA's final claim payment amount under the HH PPS is changed in accordance with the methodology described in § 484.370.

Payment year means the calendar year in which the applicable percent, a maximum upward or downward adjustment, applies.

Performance year means the calendar year during which data are collected for the purpose of calculating a competing HHA's performance on measures.

Smaller-volume cohort means the group of competing HHAs that are exempt from participation in the HHCAHPS survey in accordance with § 484.245.

Total Performance Score (TPS) means the numeric score ranging from 0 to 100 awarded to each competing HHA based on its performance under the expanded HHVBP Model.

§ 484.350 Applicability of the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General rule.* The expanded HHVBP Model applies to all Medicare-certified HHAs nationwide.

(b) *New HHAs.* For an HHA that is certified by Medicare on or after January 1, 2019, the baseline year is the first full calendar year of services beginning after the date of Medicare certification, with the exception of HHAs certified on January 1, 2019 through December 31, 2019, for which the baseline year is CY 2021, and the first performance year is the first full calendar year following the baseline year.

§ 484.355 Data reporting for measures and evaluation and the public reporting of model data under the expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) Competing home health agencies will be evaluated using a set of quality measures.

(1) *Data submission.* Except as provided in paragraph (d) of this section, and for a performance year, an HHA must submit all of the following to CMS in the form and manner, and at a time, specified by CMS:

(i) Data on measures specified under the expanded HHVBP model.

(ii) HHCAHPS Survey data. For purposes of HHCAHPS Survey data submission, the following additional requirements apply:

(A) *Survey requirements.* An HHA must contract with an approved, independent HHCAHPS survey vendor to administer the HHCAHPS survey on its behalf.

(B) *CMS approval.* CMS approves an HHCAHPS survey vendor if the applicant has been in business for a minimum of 3 years and has conducted surveys of individuals and samples for at least 2 years.

(C) *Definition of survey of individuals.* For the HHCAHPS survey, a ''survey of individuals'' is defined as the collection of data from at least 600 individuals selected by statistical sampling methods and the data collected are used for statistical purposes.

(D) *Administration of the HHCAHPS survey.* No organization, firm, or business that owns, operates, or provides staffing for an HHA is permitted to administer its own HHCAHPS Survey or administer the survey on behalf of any other HHA in the capacity as an HHCAHPS survey vendor. Such organizations are not approved by CMS as HHCAHPS survey vendors.

(E) *Compliance by HHCAHPS survey vendors.* Approved HHCAHPS survey vendors must fully comply with all HHCAHPS survey oversight activities, including allowing CMS and its HHCAHPS survey team to perform site visits at the vendors' company locations.

(F) *Patient count exemption.* An HHA that has less than 60 eligible unique HHCAHPS survey patients must annually submit to CMS its total HHCAHPS survey patient count to be exempt from the HHCAHPS survey reporting requirements for a calendar year.

(2) [Reserved]

(b) Competing home health agencies are required to collect and report such information as the Secretary determines is necessary for purposes of monitoring and evaluating the expanded HHVBP Model under section 1115A(b)(4) of the Act (42 U.S.C. 1315a).

(c) For each performance year of the expanded HHVBP Model, CMS publicly reports applicable measure benchmarks and achievement thresholds for each cohort as well as all of the following for each competing HHA that qualified for a payment adjustment for the applicable performance year on a CMS website:

(1) The Total Performance Score.

(2) The percentile ranking of the Total Performance Score.

(3) The payment adjustment percentage.

(4) Applicable measure results and improvement thresholds.

(d) CMS may grant an exception with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the HHA. CMS may grant an exception as follows:

(1) A competing HHA that wishes to request an exception with respect to quality data reporting requirements must submit its request to CMS within 90 days of the date that the extraordinary circumstances occurred. Specific requirements for submission of a request for an exception are available on the CMS website.

(2) CMS may grant an exception to one or more HHAs that have not requested an exception if CMS determines either of the following:

(i) That a systemic problem with CMS data collection systems directly affected the ability of the HHA to submit data.

(ii) That an extraordinary circumstance has affected an entire region or locale.

§ 484.360 Calculation of the Total Performance Score.

A competing HHA's Total Performance Score for a performance year is calculated as follows:

(a) CMS awards points to the competing home health agency for performance on each of the applicable measures.

(1) CMS awards greater than or equal to 0 points and less than 10 points for achievement to each competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's achievement threshold but is less than the applicable cohort's benchmark for that measure.

(2) CMS awards greater than 0 but less than 9 points for improvement to each competing home health agency whose performance on a measure during the applicable performance year exceeds the improvement threshold but is less than the applicable cohort's benchmark for that measure.

(3) CMS awards 10 points to a competing home health agency whose performance on a measure during the applicable performance year meets or exceeds the applicable cohort's benchmark for that measure.

(b) For all performance years, CMS calculates the weighted sum of points awarded for each applicable measure within each category of measures (OASIS-based, claims-based, and

HHCAHPS Survey-based) weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS Survey measure category when all three measure categories are reported, to calculate a value worth 100 percent of the Total Performance Score.

(1) Where a single measure category is not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all of the measures in the category, the remaining measure categories are reweighted such that the proportional contribution of each remaining measure category is consistent with the weights assigned when all three measure categories are available. Where two measure categories are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for all measures in those measure categories, the remaining measure category is weighted at 100 percent of the Total Performance Score.

(2) When one or more, but not all, of the measures in a measure category are not included in the calculation of the Total Performance Score for an individual HHA, due to insufficient volume for at least one measure in the category, the remaining measures in the category are reweighted such that the proportional contribution of each remaining measure is consistent with the weights assigned when all measures within the category are available.

(c) The sum of the weight-adjusted points awarded to a competing HHA for each applicable measure is the competing HHA's Total Performance Score for the calendar year. A competing HHA must have a minimum of five applicable measures to receive a Total Performance Score.

§ 484.365 Payments for home health services under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

CMS determines a payment adjustment up to the applicable percent, upward or downward, under the expanded HHVBP Model for each competing HHA based on the agency's Total Performance Score using a linear exchange function that includes all other HHAs in its cohort that received a Total Performance Score for the applicable performance year. Payment adjustments made under the expanded HHVBP Model are calculated as a percentage of otherwise-applicable payments for home health services provided under section 1895 of the Act (42 U.S.C. 1395fff).

§ 484.370 Process for determining and applying the value-based payment adjustment under the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *General.* Competing home health agencies are ranked within the larger-volume and smaller-volume cohorts nationwide based on the performance standards that apply to the expanded HHVBP Model for the baseline year, and CMS makes value-based payment adjustments to the competing HHAs as specified in this section.

(b) *Calculation of the value-based payment adjustment amount.* The value-based payment adjustment amount is calculated by multiplying the Home Health Prospective Payment final claim payment amount as calculated in accordance with § 484.205 by the payment adjustment percentage.

(c) *Calculation of the payment adjustment percentage.* The payment adjustment percentage is calculated as the product of all of the following:

(1) The applicable percent as defined in § 484.345.

(2) The competing HHA's Total Performance Score divided by 100.

(3) The linear exchange function slope.

§ 484.375 Appeals process for the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

(a) *Requests for recalculation*—(1) *Matters for recalculation.* Subject to the limitations on judicial and administrative review under section 1115A of the Act, a HHA may submit a request for recalculation under this section if it wishes to dispute the calculation of the following:

(i) Interim performance scores.

(ii) Annual total performance scores.

(iii) Application of the formula to calculate annual payment adjustment percentages.

(2) *Time for filing a request for recalculation.* A recalculation request must be submitted in writing within 15 calendar days after CMS posts the HHA-specific information on the CMS website, in a time and manner specified by CMS.

(3) *Content of request.* (i) The provider's name, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting recalculation to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for recalculation additional documentary evidence that CMS should consider. Such documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for recalculation.* In conducting the recalculation, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the recalculation.

(5) *Recalculation decision.* CMS issues a written notification of findings. A recalculation decision is subject to the request for reconsideration process in accordance with paragraph (b) of this section.

(b) *Requests for reconsideration*—(1) *Matters for reconsideration.* A home health agency may request reconsideration of the recalculation of its annual total performance score and payment adjustment percentage following a decision on the HHA's recalculation request submitted under paragraph (a) of this section, or the decision to deny the recalculation request submitted under paragraph (a).

(2) *Time for filing a request for reconsideration.* The request for reconsideration must be submitted via the CMS website within 15 calendar days from CMS' notification to the HHA contact of the outcome of the recalculation process.

(3) *Content of request.* (i) The name of the HHA, address associated with the services delivered, and CMS Certification Number (CCN).

(ii) The basis for requesting reconsideration to include the specific data that the HHA believes is inaccurate or the calculation the HHA believes is incorrect.

(iii) Contact information for a person at the HHA with whom CMS or its agent can communicate about this request, including name, email address, telephone number, and mailing address (must include physical address, not just a post office box).

(iv) The HHA may include in the request for reconsideration additional documentary evidence that CMS should consider. The documents may not include data that was to have been filed by the applicable data submission deadline, but may include evidence of timely submission.

(4) *Scope of review for reconsideration.* In conducting the reconsideration review, CMS reviews the applicable measures and performance scores, the evidence and findings upon which the determination was based, and any additional documentary evidence submitted by the HHA. CMS may also review any other evidence it believes to be relevant to the reconsideration. The HHA must prove its case by a preponderance of the evidence with respect to issues of fact.

(5) *Reconsideration decision.* CMS reconsideration officials issue a written final determination.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 19. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 20. Section 488.2 is amended by adding provision ''1822'' in numerical order to read as follows:

§ 488.2 Statutory basis.

* * * * *

1822—Hospice Program survey and enforcement procedures.

* * * * *

■ 21. Section 488.5 is amended by adding paragraph (a)(4)(x) to read as follows:

§ 488.5 Application and re-application procedures for national accrediting organizations.

* * * * *

(a) * * *

(4) * * *

(x) For accrediting organizations applying for approval or re-approval of CMS-approved hospice programs, a statement acknowledging that the AO will include a statement of deficiencies (that is, the Form CMS–2567 or a successor form) to document findings of the hospice Medicare conditions of participation in accordance with section 1822(a)(2)(A)(ii) of the Act and will submit such in a manner specified by CMS.

* * * * *

■ 22. Section 488.7 is amended by revising paragraph (b) by adding paragraph (c) to read as follows.

§ 488.7 Release and use of accreditation surveys.

* * * * *

(b) With the exception of home health agency and hospice program surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publicly disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

(c) CMS posts inspection reports from a State or local survey agency or accreditation organization conducted on or after October 1, 2022, for hospice programs, including copies of a hospice program's survey deficiencies, and enforcement actions (for example, involuntary terminations) taken as a result of such surveys, on its public website in a manner that is prominent, easily accessible, readily understandable, and searchable for the general public and allows for timely updates.

■ 23. Section 488.28 is amended by revising the section heading to read as follows:

§ 488.28 Providers or suppliers, other than SNFs, NFs, HHAs, and Hospice programs with deficiencies.

* * * * *

■ 24. Add subparts M and N to read as follows:

Subpart M—Survey and Certification of Hospice Programs

Sec.

488.1100 Basis and scope.
488.1105 Definitions.
488.1110 Hospice program: surveys and hotline.
488.1115 Surveyor qualifications and prohibition of conflicts of interest.
488.1120 Survey teams.
488.1125 Consistency of survey results.
488.1130 Special focus program.

Subpart N—Enforcement Remedies for Hospice Programs with Deficiencies

Sec.

488.1200 Statutory basis.
488.1205 Definitions.
488.1210 General provisions.
488.1215 Factors to be considered in selecting remedies.
488.1220 Available remedies.
488.1225 Action when deficiencies pose immediate jeopardy.
488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.
488.1235 Temporary management.
488.1240 Suspension of all or part of the payments.
488.1245 Civil money penalties.
488.1250 Directed plan of correction.
488.1255 Directed in-service training.
488.1260 Continuation of payments to a hospice program with deficiencies.
488.1265 Termination of provider agreement.

Subpart M—Survey and Certification of Hospice Programs

§ 488.1100 Basis and scope.

Sections 1812, 1814, 1822, 1861, 1864, and 1865 of the Act establish requirements for Hospice programs and to authorize surveys to determine whether they meet the Medicare conditions of participation.

§ 488.1105 Definitions.

As used in this subpart—

Abbreviated standard survey means a focused survey other than a standard survey that gathers information on hospice program's compliance with specific standards or conditions of participation. An abbreviated standard survey may be based on complaints received or other indicators of specific concern.

Complaint survey means a survey that is conducted to investigate substantial allegations of noncompliance as defined in § 488.1.

Condition-level deficiency means noncompliance as described in § 488.24.

Deficiency is a violation of the Act and regulations contained in part 418, subparts C and D of this chapter, is determined as part of a survey, and can be either standard or condition-level.

Noncompliance means any deficiency found at the condition-level or standard-level.

Standard-level deficiency means noncompliance with one or more of the standards that make up each condition of participation for hospice programs.

Standard survey means a survey conducted in which the surveyor reviews the hospice program's compliance with a select number of standards or conditions of participation or both to determine the quality of care and services furnished by a hospice program.

Substantial compliance means compliance with all condition-level requirements, as determined by CMS or the State.

§ 488.1110 Hospice program: surveys and hotline.

(a) *Basic period.* Each hospice program as defined in section 1861(dd) of the Act is subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months. Additionally, a survey may be conducted as frequently as necessary to—

(1) Assure the delivery of quality hospice program services by determining whether a hospice program complies with the Act and conditions of participation; and

(2) Confirm that the hospice program has corrected deficiencies that were previously cited.

(b) *Complaints.* A standard survey, or abbreviated standard survey—

(1) Must be conducted of a hospice program when complaints against the hospice program are reported to CMS, the State, or local agency.

(2) The State, or local agency is responsible for maintaining a toll-free hotline to collect, maintain, and continually update information on Medicare-participating hospice programs including significant deficiencies found regarding patient care, corrective actions, and remedy activity during its most recent survey, and to receive complaints and answer questions about hospice programs. The State or local agency is also responsible for maintaining a unit for investigating such complaints.

§ 488.1115 Surveyor qualifications and prohibition of conflicts of interest.

(a) *Minimum qualifications:* Surveyors must meet minimum qualifications prescribed by CMS. Before any accrediting organization, State or Federal surveyor may serve on a hospice survey team (except as a trainee), he/she must have successfully completed the relevant CMS-sponsored Basic Hospice Surveyor Training Course, and additional training as specified by CMS.

(b) *Disqualifications.* Any of the following circumstances disqualifies a surveyor from surveying a particular hospice program:

(1) The surveyor currently serves, or, within the previous 2 years has served, with the hospice program to be surveyed as one of the following:

(i) A direct employee.

(ii) An employment agency staff at the hospice program.

(iii) An officer, consultant, or agent for the hospice program to be surveyed concerning compliance with conditions of participation specified in or in accordance with sections 1861(dd) of the Act.

(2) The surveyor has a financial interest or an ownership interest in the hospice program to be surveyed.

(3) The surveyor has an immediate family member, as defined at. § 411.351 of this chapter, who has a financial interest or an ownership interest with the hospice program to be surveyed.

(4) The surveyor has an immediate family member, as defined at § 411.351 of this chapter, who is a patient of the hospice program to be surveyed.

§ 488.1120 Survey teams.

Standard surveys conducted by more than one surveyor must be conducted by a multidisciplinary team of professionals typically involved in hospice care and identified as professionals providing hospice core services at § 418.64 of this chapter. The multidisciplinary team must include a registered nurse. Surveys conducted by a single surveyor, must be conducted by a registered nurse.

§ 488.1125 Consistency of survey results.

A survey agency or accrediting organization must provide a corrective action plan to CMS for any disparity rates that are greater than the threshold established by CMS.

§ 488.1130 Special focus program.

(a) *In general.*—The Secretary must conduct a special focus program for the enforcement of conditions of participation for hospice programs that the Secretary has identified as having substantially failed to meet applicable requirements for Medicare participation.

(b) *Criteria for inclusion in the hospice special focus program.* (1) A hospice program may be required to participate in a special focus program if any one of the following criteria exists:

(i) The hospice program is found to be deficient with condition-level findings during two consecutive standard surveys.

(ii) The hospice program is found to be deficient with condition-level findings during two consecutive complaint surveys.

(iii) The hospice program is found to be deficient with two or more condition-level findings during a validation survey.

(2) CMS provides the State survey agencies with a list of hospice programs identified as meeting the criteria for inclusion in the special focus program. A program that meets the criteria will be placed on the special focus program candidate list and selected for the program as specified by CMS.

(c) *Periodic surveys.* The State Survey Agency, on CMS's behalf, conducts an onsite survey of each hospice in the program not less than once every 6 months to examine all the Medicare hospice program conditions of participation and recommend progressive enforcement in accordance with an enforcement remedy or remedies until the hospice program either of the following:

(1) Graduates from the special focus program by coming back into full compliance with the hospice conditions of participation on two consecutive 6-month surveys.

(2) Is terminated from the Medicare or Medicaid or both programs.

Subpart N—Enforcement Remedies for Hospice Programs with Deficiencies

§ 488.1200 Statutory basis.

Section 1822 of the Act authorizes the Secretary to take actions to remove and correct deficiencies in a hospice program through an enforcement remedy or termination or both. This section specifies that these remedies are in addition to any others available under State or Federal law, and, except for the final determination of civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.1205 Definitions.

As used in this subpart—

Directed plan of correction means CMS or the temporary manager (with CMS/SA approval) may direct the hospice program to take specific corrective action to achieve specific outcomes within specific timeframes.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient(s).

New admission means an individual who becomes a patient or is readmitted to the hospice program on or after the effective date of a suspension of payment remedy.

Per instance means a single event of noncompliance identified and corrected during a survey, for which the statute authorizes CMS to impose a remedy.

Plan of correction means a plan developed by the hospice program and approved by CMS that is the hospice program's written response to survey findings detailing corrective actions to cited deficiencies and specifies the date by which those deficiencies will be corrected.

Repeat deficiency means a condition-level deficiency that is cited on the current survey and is substantially the same as or similar to, a finding of a standard-level or condition-level deficiency cited on the most recent previous standard survey or on any intervening survey since the most recent standard survey. Repeated non-compliance is not on the basis that the exact regulation (that is, tag number) for the deficiency was repeated.

Temporary management means the temporary appointment by CMS or by a CMS authorized agent, of a substitute manager or administrator. The hospice program's governing body must ensure that the temporary manager has authority to hire, terminate or reassign staff, obligate funds, alter procedures, and manage the hospice program to

correct deficiencies identified in the hospice program's operation.

§ 488.1210 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements in order to protect the health and safety of individuals under the care of a hospice program.

(b) *Basis for imposition of remedies.* When CMS chooses to apply one or more remedies specified in § 488.1220, the remedies are applied on the basis of noncompliance with one or more conditions of participation and may be based on failure to correct previous deficiency findings as evidenced by repeat condition-level deficiencies.

(c) *Number of remedies.* CMS may impose one or more remedies specified in § 488.1220 of this part for each condition-level deficiency constituting noncompliance.

(d) *Plan of correction requirement.* Regardless of which remedy is applied, a non-compliant hospice program must submit a plan of correction for approval by CMS or the State Survey Agency.

(e) *Notification requirements*—(1) *Notice of intent.* CMS provides written notification to the hospice program of the intent to impose the remedy, the statutory basis for the remedy, the nature of the noncompliance, the proposed effective date of the sanction, and the appeal rights. For payment suspensions, the notice of intent would also identify which payments are being suspended, and for civil money penalties, the notice of intent would also include the amount being imposed.

(2) *Final notice.* With respect to civil money penalties, CMS provides a written final notice to the hospice program, as set forth in § 488.1245(e), once the administrative determination is final.

(3) *Date of enforcement action.* The notice periods specified in § 488.1225(b) and § 488.1230(b) begin the day after the hospice receives the notice of intent.

(f) *Appeals.* (1) The hospice program may request a hearing on a determination of noncompliance leading to the imposition of a remedy, including termination of the provider agreement, under the provisions of part 498 of this chapter.

(2) A pending hearing does not delay the effective date of a remedy, including termination, against a hospice program. Remedies continue to be in effect regardless of the timing of any appeals proceedings.

§ 488.1215 Factors to be considered in selecting remedies.

CMS bases its choice of remedy or remedies on consideration of one or more factors that include, but are not limited to, the following:

(a) The extent to which the deficiencies pose immediate jeopardy to patient health and safety.

(b) The nature, incidence, manner, degree, and duration of the deficiencies or noncompliance.

(c) The presence of repeat deficiencies, the hospice program's overall compliance history and any history of repeat deficiencies at either the parent hospice program or any of its multiple locations.

(d) The extent to which the deficiencies are directly related to a failure to provide quality patient care.

(e) The extent to which the hospice program is part of a larger organization with performance problems.

(f) An indication of any system-wide failure to provide quality care.

§ 488.1220 Available remedies.

The following enforcement remedies are available instead of, or in addition to, termination of the hospice program's provider agreement under § 489.53, for a period not to exceed 6 months:

(a) Civil money penalties.

(b) Suspension of payment for all or part of the payments.

(c) Temporary management of the hospice program.

(d) Directed plan of correction.

(e) Directed in-service training.

§ 488.1225 Action when deficiencies pose immediate jeopardy.

(a) *Immediate jeopardy.* If there is immediate jeopardy to the hospice program's patient health or safety, the following rules apply:

(1) CMS immediately terminates the hospice program provider agreement in accordance with § 489.53 of this chapter.

(2) CMS terminates the hospice program provider agreement no later than 23 calendar days from the last day of the survey, if the immediate jeopardy has not been removed by the hospice program.

(3) In addition to a termination, CMS may impose one or more enforcement remedies, as appropriate.

(b) *2-day notice.* Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is immediate jeopardy, notice must be given at least 2 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1225(e).

(c) *Transfer of care.* A hospice program, if its provider agreement is terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination.

§ 488.1230 Action when deficiencies are at the condition-level but do not pose immediate jeopardy.

(a) *Noncompliance with conditions of participation.* If the hospice program is no longer in compliance with the conditions of participation, either because the condition-level deficiency or deficiencies substantially limit the provider's capacity to furnish adequate care but do not pose immediate jeopardy, or the hospice program has repeat condition-level deficiencies based on the hospice program's failure to correct and sustain compliance, CMS does either of the following.

(1) Terminates the hospice program's provider agreement.

(2) Imposes one or more enforcement remedies set forth in § 488.1220(a) through (e) in lieu of termination, for a period not to exceed 6 months.

(b) *15-day notice.* Except for civil money penalties, for all remedies specified in § 488.1220 imposed when there is no immediate jeopardy, notice must be given at least 15 calendar days before the effective date of the enforcement action. The requirements of the notice are set forth in § 488.1210(e).

(c) *Not meeting criteria for continuation of payment.* If a hospice program does not meet the criteria for continuation of payment under § 488.1260(a), CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(d) *Termination timeframe when there is no immediate jeopardy.* CMS terminates a hospice program within 6 months of the last day of the survey, if the hospice program is not in compliance with the conditions of participation, and the terms of the plan of correction have not been met.

(e) *Transfer of care.* A hospice program, if its provider agreement terminated, is responsible for providing information, assistance, and arrangements necessary for the proper and safe transfer of patients to another local hospice program within 30 calendar days of termination. The State must assist the hospice program in the safe and orderly transfer of care and services for the patients to another local hospice program.

§ 488.1235 Temporary management.

(a) *Application.* (1) CMS may impose temporary management of a hospice program if it determines that a hospice program has a condition-level deficiency and CMS determines that management limitations or the

deficiencies are likely to impair the hospice program's ability to correct the noncompliance and return the hospice program to compliance with all of the conditions of participation within the timeframe required.

(b) *Procedures*—(1) *Notice of intent.* Before imposing this remedy, CMS notifies the hospice program in accordance with § 488.1210(e) that a temporary manager is being appointed.

(2) *Termination.* If the hospice program fails to relinquish authority and control to the temporary manager, CMS terminates the hospice program's provider agreement in accordance with § 488.1265.

(c) *Duration and effect of remedy.* Temporary management continues until one of the following occur:

(1) CMS determines that the hospice program has achieved substantial compliance and has the management capability to ensure continued compliance with all the conditions of participation.

(2) CMS terminates the provider agreement.

(3) The hospice program resumes management control without CMS approval. In this case, CMS initiates termination of the provider agreement and may impose additional remedies.

(4) Temporary management will not exceed a period of 6 months from the date of the survey identifying noncompliance.

(d) *Payment of salary.* (1) The temporary manager's salary must meet the following:

(i) Is paid directly by the hospice program while the temporary manager is assigned to that hospice program.

(ii) Must be at least equivalent to the sum of the following:

(A) The prevailing salary paid by providers for positions of this type in what the State considers to be the hospice program's geographic area (prevailing salary based on the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates)).

(B) Any additional costs that would have reasonably been incurred by the hospice program if such person had been in an employment relationship.

(C) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(2) A hospice program's failure to pay the salary and other costs of the temporary manager described in paragraph (d)(1) of this section is considered a failure to relinquish authority and control to temporary management.

§ 488.1240 Suspension of all or part of the payments.

(a) *Application.* (1) CMS may suspend all or part of the payments to which a hospice program would otherwise be entitled with respect to items and services furnished by a hospice program on or after the date on which the Secretary determines that remedies should be imposed.

(2) CMS considers this remedy for any deficiency related to poor patient care outcomes, regardless of whether the deficiency poses immediate jeopardy.

(b) *Procedures*—(1) *Notice of intent.* (i) Before suspending payments, CMS provides the hospice program notice of the suspension of payment in accordance with § 488.1210(e).

(ii) The hospice program may not charge a newly admitted hospice patient who is a Medicare beneficiary for services for which Medicare payment is suspended unless the hospice program can show that, before initiating care, it gave the patient or his or her representative oral and written notice of the suspension of Medicare payment in a language and manner that the beneficiary or representative can understand.

(2) *Restriction.* (i) Suspension of payment remedy may be imposed anytime a hospice program is found to be out of substantial compliance with the conditions of participation.

(ii) Suspension of payment remains in place until CMS determines that the hospice program has achieved substantial compliance with the conditions of participation or is terminated, as determined by CMS.

(3) *Resumption of payments.* Payments to the hospice program resume prospectively on the date that CMS determines that the hospice program has achieved substantial compliance with the conditions of participation.

(c) *Duration and effect of remedy.* This remedy ends when any of the following occur:

(1) CMS determines that the hospice program has achieved substantial compliance with all of the conditions of participation.

(2) When the hospice program is terminated or CMS determines that the hospice program is not in compliance with the conditions of participation at a maximum of 6 months from the date of the survey identifying the noncompliance.

§ 488.1245 Civil money penalties.

(a) *Application.* (1) CMS may impose a civil money penalty against a hospice program for either the number of days the hospice program is not in compliance with one or more conditions of participation or for each instance that a hospice program is not in compliance, regardless of whether the hospice program's deficiencies pose immediate jeopardy.

(2) CMS may impose a civil money penalty for the number of days of immediate jeopardy.

(3) A per-day and a per-instance CMP may not be imposed simultaneously for the same deficiency in conjunction with a survey.

(4) CMS may impose a civil money penalty for the number of days of noncompliance since the last standard survey, including the number of days of immediate jeopardy.

(b) *Amount of penalty*—(1) *Factors considered.* CMS takes into account the following factors in determining the amount of the penalty:

(i) The factors set out at § 488.1215.

(ii) The size of a hospice program and its resources.

(iii) Evidence that the hospice program has a built-in, self-regulating quality assessment and performance improvement system to provide proper care, prevent poor outcomes, control patient injury, enhance quality, promote safety, and avoid risks to patients on a sustainable basis that indicates the ability to meet the conditions of participation and to ensure patient health and safety.

(2) *Adjustments to penalties.* Based on revisit survey findings, adjustments to penalties may be made after a review of the provider's attempted correction of deficiencies.

(i) CMS may increase a CMP in increments based on a hospice program's inability or failure to correct deficiencies, the presence of a system-wide failure in the provision of quality care, or a determination of immediate jeopardy with actual harm versus immediate jeopardy with potential for harm.

(ii) CMS may also decrease a CMP in increments to the extent that it finds, in accordance with a revisit, that substantial and sustainable improvements have been implemented even though the hospice program is not yet in compliance with the conditions of participation.

(iii) No penalty assessment exceeds $10,000, as adjusted annually under 45 CFR part 102, for each day a hospice program is not in substantial compliance with one or more conditions of participation.

(3) *Upper range of penalty.* Penalties in the upper range of $8,500 to $10,000 per day, as adjusted annually under 45 CFR part 102, are imposed for a condition-level deficiency that is

immediate jeopardy. The penalty in this range continues until substantial compliance can be determined based on a revisit survey.

(i) $10,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in actual harm.

(ii) $9,000, as adjusted annually under 45 CFR part 102, per day for a deficiency or deficiencies that are immediate jeopardy and that result in a potential for harm.

(iii) $8,500, as adjusted annually under 45 CFR part 102, per day for a deficiency based on an isolated incident in violation of established hospice policy.

(4) *Middle range of penalty.* Penalties in the range of $1,500 up to $8,500, as adjusted annually under 45 CFR part 102, per day of noncompliance are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy but is directly related to poor quality patient care outcomes.

(5) *Lower range of penalty.* Penalties in this range of $500 to $4,000, as adjusted annually under 45 CFR part 102, are imposed for a repeat or condition-level deficiency or both that does not constitute immediate jeopardy and that are related predominately to structure or process-oriented conditions rather than directly related to patient care outcomes.

(6) *Per instance penalty.* Penalty imposed per instance of noncompliance may be assessed for one or more singular events of condition-level deficiency that are identified and where the noncompliance was corrected during the onsite survey. When penalties are imposed for per instance of noncompliance, or more than one per instance of noncompliance, the penalties will be in the range of $1,000 to $10,000 per instance, not to exceed $10,000 each day of noncompliance, as adjusted annually under 45 CFR part 102.

(7) *Decreased penalty amounts.* If the immediate jeopardy situation is removed, but a condition-level deficiency exists, CMS shifts the penalty amount imposed per day from the upper range to the middle or lower range. An earnest effort to correct any systemic causes of deficiencies and sustain improvement must be evident.

(8) *Increased penalty amounts.* (i) In accordance with paragraph (b)(2) of this section, CMS increases the per day penalty amount for any condition-level deficiency or deficiencies which, after imposition of a lower-level penalty amount, become sufficiently serious to pose potential harm or immediate jeopardy.

(ii) CMS increases the per day penalty amount for deficiencies that are not corrected and found again at the time of revisit survey(s) for which a lower-level penalty amount was previously imposed.

(iii) CMS may impose a more severe amount of penalties for repeated noncompliance with the same condition-level deficiency or uncorrected deficiencies from a prior survey.

(c) *Procedures*—(1) *Notice of intent.* CMS provides the hospice program with written notice of the intent to impose a civil money penalty in accordance with § 488.1210(e).

(2) *Appeals*—(i) *Appeals procedures.* A hospice program may request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty. The request must meet the requirements in § 498.40 of this chapter.

(ii) *Waiver of a hearing.* A hospice program may waive the right to a hearing, in writing, within 60 calendar days from the date of the notice imposing the civil money penalty. If a hospice program timely waives its right to a hearing, CMS reduces the penalty amount by 35 percent, and the amount is due within 15 calendar days of the hospice program agreeing in writing to waive the hearing. If the hospice program does not waive its right to a hearing in accordance to the procedures specified in this section, the civil money penalty is not reduced by 35 percent.

(d) *Accrual and duration of penalty*—(1) *Accural of per day penalty.* (i) The per day civil money penalty may start accruing as early as the beginning of the last day of the survey that determines that the hospice program was out of compliance, as determined by CMS.

(ii) A civil money penalty for each per instance of noncompliance is imposed in a specific amount for that particular deficiency, with a maximum of $10,000 per day per hospice program.

(2) *Duration of per day penalty when there is immediate jeopardy.* (i) In the case of noncompliance that poses immediate jeopardy, CMS must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy is not removed.

(ii) A penalty imposed per day of noncompliance will stop accruing on the day the provider agreement is terminated or the hospice program achieves substantial compliance, whichever occurs first.

(3) *Duration of penalty when there is no immediate jeopardy.* (i) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice of intent specified in paragraph (c)(1) of this section and an additional period of no longer than 6 months following the last day of the survey.

(ii) If the hospice program has not achieved compliance with the conditions of participation within 6 months following the last day of the survey, CMS terminates the provider agreement. The accrual of civil money penalty stops on the day the hospice program agreement is terminated or the hospice program achieves substantial compliance, whichever is earlier.

(e) *Computation and notice of total penalty amount.* (1) When a civil money penalty is imposed on a per day basis and the hospice program achieves compliance with the conditions of participation as determined by a revisit survey, once the administrative determination is final, CMS sends a final notice to the hospice program containing of the following information:

(i) The amount of penalty assessed per day.

(ii) The total number of days of noncompliance.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(2) When a civil money penalty is imposed per instance of noncompliance, once the administrative determination is final, CMS sends a final notice to the hospice program containing all of the following information:

(i) The amount of the penalty that was assessed.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest to be assessed on any unpaid balance beginning on the due date, as provided in paragraph (f)(6) of this section.

(3) In the case of a hospice program for which the provider agreement has been involuntarily terminated, CMS sends the final notice after one of the following actions has occurred:

(i) The administrative determination is final.

(ii) The hospice program has waived its right to a hearing in accordance with paragraph (c)(2)(ii) of this section.

(iii) Time for requesting a hearing has expired and the hospice program has not requested a hearing.

(f) *Due date for payment of penalty.* A penalty is due and payable 15 calendar days from notice of the final administrative decision.

(1) Payments are due for all civil money penalties within 15 calendar days of any of the following:

(i) After a final administrative decision when the hospice program achieves substantial compliance before the final decision or the effective date of termination occurs before the final decision.

(ii) After the time to appeal has expired and the hospice program does not appeal or fails to timely appeal the initial determination.

(iii) After CMS receives a written request from the hospice program requesting to waive its right to appeal the determinations that led to the imposition of a remedy.

(iv) After the effective date of termination.

(2) A request for hearing does not delay the imposition of any penalty; it only potentially delays the collection of the final penalty amount.

(3) If a hospice program waives its right to a hearing according to paragraph (c)(2)(ii) of this section, CMS applies a 35 percent reduction to the CMP amount for any of the following:

(i) The hospice program achieved compliance with the conditions of participation before CMS received the written waiver of hearing.

(ii) The effective date of termination occurs before CMS received the written waiver of hearing.

(4) The period of noncompliance may not extend beyond 6 months from the last day of the survey.

(5) The amount of the penalty, when determined, may be deducted (offset) from any sum then or later owing by CMS or State Medicaid to the hospice program.

(6) Interest is assessed and accrues on the unpaid balance of a penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(g) *Review of the penalty.* When an administrative law judge finds that the basis for imposing a civil monetary penalty exists, as specified in this part, the administrative law judge, may not do any of the following:

(1) Set a penalty of zero or reduce a penalty to zero.

(2) Review the exercise of discretion by CMS to impose a civil monetary penalty.

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (b) of this section.

§ 488.1250 Directed plan of correction.

(a) *Application.* CMS may impose a directed plan of correction when a hospice program—

(1) Has one or more condition-level deficiencies that warrant directing the hospice program to take specific actions; or

(2) Fails to submit an acceptable plan of correction.

(b) *Procedures.* (1) Before imposing this remedy, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) CMS or the temporary manager (with CMS approval) may direct the hospice program to take corrective action to achieve specific outcomes within specific timeframes.

(c) *Duration and effect of remedy.* If the hospice program fails to achieve compliance with the conditions of participation within the timeframes specified in the directed plan of correction, which may not to exceed 6 months, CMS does one of the following:

(1) May impose one or more other remedies set forth in § 488.1220.

(2) Terminates the provider agreement.

§ 488.1255 Directed in-service training.

(a) *Application.* CMS may require the staff of a hospice program to attend in-service training program(s) if CMS determines all of the following:

(1) The hospice program has condition-level deficiencies.

(2) Education is likely to correct the deficiencies.

(3) The programs are conducted by established centers of health education and training or consultants with background in education and training with Medicare hospice providers, or as deemed acceptable by CMS or the State (by review of a copy of curriculum vitas or resumes and references to determine the educator's qualifications).

(b) *Procedures*—(1) *Notice of intent.* Before imposing this remedy, CMS notifies the hospice program in accordance with § 488.1210(e).

(2) *Action following training.* After the hospice program staff has received in-service training, if the hospice program has not achieved substantial compliance, CMS may impose one or more other remedies specified in § 488.1220.

(3) *Payment.* The hospice program pays for the directed in-service training for its staff.

§ 488.1260 Continuation of payments to a hospice program with deficiencies.

(a) *Continued payments.* CMS may continue payments to a hospice program with condition-level deficiencies that do not constitute immediate jeopardy for up to 6 months from the last day of the survey if the criteria in paragraph (a)(1) of this section are met.

(1) *Criteria.* CMS may continue payments to a hospice program not in compliance with the conditions of participation for the period specified in paragraph (a) of this section if all of the following criteria are met:

(i) An enforcement remedy, or remedies, (with the exception of suspension of all payment) has been imposed on the hospice program and termination has not been imposed.

(ii) The hospice program has submitted a plan of correction approved by CMS.

(iii) The hospice program agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) *Termination.* CMS may terminate the hospice program's provider agreement any time if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments for new admissions.* If termination is imposed, either on its own or in addition to an enforcement remedy or remedies, or if any of the criteria set forth in paragraph (a)(1) of this section are not met, the hospice program will receive no Medicare payments, as applicable, for new admissions following the last day of the survey.

(c) *Failure to achieve compliance with the conditions of participation.* If the hospice program does not achieve compliance with the conditions of participation by the end of the period specified in paragraph (a) of this section, CMS terminates the provider agreement of the hospice program in accordance with § 488.1265.

§ 488.1265 Termination of provider agreement.

(a) *Effect of termination by CMS.* Termination of the provider agreement ends—

(1) Payment to the hospice program; and

(2) Any enforcement remedy.

(b) *Basis for termination.* CMS terminates a hospice program's provider agreement under any one of the following conditions:

(1) The hospice program is not in compliance with the conditions of participation.

(2) The hospice program fails to submit an acceptable plan of correction within the timeframe specified by CMS.

(3) The hospice program fails to relinquish control to the temporary manager, if that remedy is imposed by CMS.

(4) The hospice program fails to meet the eligibility criteria for continuation of payment as set forth in § 488.1260(a)(1).

(c) *Notice.* CMS notifies the hospice program and the public of the termination, in accordance with procedures set forth in § 489.53 of this chapter.

(d) *Procedures for termination.* CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter.

(e) *Payment post termination.* Payment is available for up to 30 calendar days after the effective date of termination for hospice care furnished under a plan established before the effective date of termination as set forth in § 489.55 of this chapter.

(f) *Appeal.* A hospice program may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 25. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 26. Section 489.28 is amended by revising paragraphs (d) and (e) to read as follows:

§ 489.28 Special capitalization requirements for HHAs

* * * * *

(d) *Required proof of availability of initial reserve operating funds.* The HHA must provide CMS with adequate proof of the availability of initial reserve operating funds. Such proof, at a minimum, will include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution (if the financial institution offers such attestations) that the funds are in the account(s) and that the funds are immediately available to the HHA. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial 3-month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds. As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS later may require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds is non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

(e) *Borrowed funds.* If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution (if the financial institution offers such attestations) that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

* * * * *

§ 489.53 [Amended]

■ 27. Section 489.53 is amended in paragraph (a)(17) by removing the phrase ''an HHA,'' and adding in its place the phrase ''an HHA or hospice program,''.

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFS/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 28. The authority citation for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7j, and 1395hh.

■ 29. Section 498.1 is amended by adding paragraph (l) to read as follows:

§ 498.1 Statutory basis.

* * * * *

(l) Section 1822 of the Act provides that for hospice programs that are no longer in compliance with the conditions of participation, the Secretary may develop remedies to be imposed instead of, or in addition to, termination of the hospice program's Medicare provider agreement.

■ 30. Section 498.3 is amended—

■ a. By revising paragraph (b)(13);

■ b. In paragraph (b)(14) introductory text, by removing the phrase ''NF or HHA but only'' and adding in its place the phrase ''NF, HHA or hospice program, but only'';

■ c. By revising paragraph (b)(14)(i); and

■ d. In paragraph (d)(10) introductory text, by removing the phrase ''NF or HHA—'' and adding in its place the phrase ''NF, HHA or hospice program—''.

The revisions read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * *

(13) Except as provided at paragraph (d)(12) of this section for SNFs, NFs, HHAs, and hospice programs, the finding of noncompliance leading to the imposition of enforcement actions specified in § 488.406, § 488.820, or § 488.1170 of this chapter, but not the determination as to which sanction or remedy was imposed. The scope of review on the imposition of a civil money penalty is specified in § 488.438(e), § 488.845(h), or § 488.1195(h) of this chapter.

(14) * * *

(i) The range of civil money penalty amounts that CMS could collect (for SNFs or NFs, the scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter and for HHAs and hospice programs, the scope of review during a hearing on the imposition of a civil money penalty is set forth in

§§ 488.845(h) and 488.1195(h) of this chapter); or

* * * * *

§ 498.60 [Amended]

■ 31. Section 498.60 is amended—

■ a. In paragraph (c)(1) by removing the reference ''§§ 488.438(e) and 488.845(h)'' and adding in its place the reference ''§§ 488.438(e), 488.845(h), and 488.1195(g)''.

■ b. In paragraph (c)(2) by removing the phrase ''or HHA'' and adding in its place the phrase ''HHA or hospice program''.

Dated: June 23, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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