DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424, 483, and 484

[CMS–1803–P]

RIN 0938–AV28

Medicare Program; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would set forth routine updates to the Medicare home health payment rates; the payment rate for the disposable negative pressure wound therapy (dNPWT) devices; and the intravenous immune globulin (IVIG) items and services payment rate for CY 2025 in accordance with existing statutory and regulatory requirements. In addition, it proposes changes to the Home Health Quality Reporting Program (HH QRP) requirements and provides an update on potential approaches for integrating health equity in the Expanded Health Value Based Purchasing (HHVBP) Model. It also proposes a new standard for acceptance to service policy in the HH conditions of participation (CoPs) and includes requests for information (RFIs) soliciting input on permitting rehabilitative therapists to conduct the initial and comprehensive assessment and the factors that may influence the patient referral and intake processes. Lastly, it proposes updates to provider and supplier enrollment requirements and changes to the long-term care reporting requirements for acute respiratory illnesses.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on August 26, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1803–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

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

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1803–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 via express or overnight mail to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1803–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

FOR FURTHER INFORMATION CONTACT: Brian Slater, (410) 786–5229, for home health and home IVIG payment inquiries.

For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to *HomeHealthPolicy@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 more information about the expanded Home Health Value-Based Purchasing Model, please visit the Expanded HHVBP Model web page at *https://innovation.cms.gov/innovation-models/expanded-home-health-value-based-purchasing-model.*

Frank Whelan (410) 786–1302, for Medicare provider and supplier enrollment inquiries.

Mary Rossi-Coajou at *mary.rossi-coajou@cms.hhs.gov* or Molly Anderson at *molly.anderson@cms.hhs.gov,* for more information about the home health conditions of participation (HH CoPs).

Kim Roche (*kim.roche1@cms.hhs.gov*), for more information about the long-term care requirements for participation.

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: *https://www.regulations.gov/.* Follow the search instructions on that website to view public comments.

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I. Executive Summary

A. Purpose and Legal Authority

1. Home Health Prospective Payment System (HH PPS)

As required under section 1895(b) of the Social Security Act (the Act), this proposed rule would update the CY 2025 payment rates for home health agencies (HHAs) and the CY 2025 payment rate for the disposable negative pressure wound therapy (dNPWT) device. In this proposed rule, we include analysis on home health utilization, as well as analysis 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 Patient Driven Groupings Model (PDGM) case-mix adjustment methodology. This rule proposes a crosswalk for mapping the Outcome and Assessment Information Set-D (OASIS–D) data elements to the equivalent OASIS–E data elements for use in the methodology to analyze the difference between assumed versus actual behavior change on estimated aggregate expenditures and proposes a permanent prospective behavior adjustment to the CY 2025 home health payment rate. In addition, this rule proposes to recalibrate the PDGM case-mix weights and to update the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for 30-day periods of care in CY 2025; proposes to adopt the most recent Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) delineations for the home health wage index; and proposes an occupational therapy (OT) LUPA add-on factor and updates to the physical therapy (PT), speech-language pathology (SLP), and skilled nursing (SN) LUPA add-on factors. Additionally, this rule proposes to update the CY 2025 fixed-dollar loss ratio (FDL) for outlier payments (so that outlier payments as a percentage of estimated total payments are projected not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act).

2. Home Health (HH) Quality Reporting Program (QRP)

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are proposing updated policies. We are proposing to add four new assessment items and to modify one assessment item on the OASIS, an update to the removal of the suspension of OASIS all-payer data collection, and we are seeking information on future HH QRP quality measure (QM) concepts.

3. Expanded Home Health Value-Based Purchasing (HHVBP) Model

In accordance with the statutory authority at section 1115A of the Act, we are doing the following for the expanded HHVBP Model: (1) providing an update on potential approaches for integrating health equity that are being considered; and (2) including a request for information (RFI) related to future performance measure concepts.

4. Home Intravenous Immune Globulin (IVIG) Items and Services

In section V.D.1. of this proposed rule, we propose a rate update for the CY 2025 IVIG items and services payment under the home intravenous immune globulin (IVIG) benefit.

5. Home Health CoP Changes

In section VI. A. of this proposed rule, we are proposing to add a new standard at § 484.105(i) that would require HHAs to develop, consistently apply, and maintain an acceptance to service policy, including specified factors, that would govern the process for accepting patients to service. We also propose that HHAs would be required to make specified information about their services and service limitations available to the public. Section VI.B. of this proposed rule includes an RFI to obtain information from stakeholders on whether CMS should shift its longstanding policy and permit rehabilitative therapists to conduct the initial and comprehensive assessment for cases that have both therapy and nursing services ordered as part of the plan of care. In addition, we are seeking public comments on other factors that influence the patient referral and intake processes.

6. Provider and Supplier Enrollment Requirements

In accordance with section 1866(j)(3)(A) of the Act, we are proposing to revise our requirements in 42 CFR 424.527(a) regarding the application of provisional periods of enhanced oversight (PPEO). Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. We are proposing to expand the definition of ''new provider or supplier'' (solely for purposes of applying a PPEO) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges.

7. Long-Term Care (LTC) Requirements for Acute Respiratory Illness Reporting

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents. As such, we are proposing streamlined weekly data reporting requirements for certain respiratory illnesses. We are also proposing additional, related data elements that could be activated in the event of a future acute respiratory illness public health emergency (PHE).

B. Summary of the Provisions of This Proposed Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this proposed rule, we provide monitoring and data analysis on PDGM utilization.

In section II.C.1 of this proposed rule, we propose a permanent adjustment to the base payment rate under the HH PPS. Additionally, we propose a

crosswalk for mapping the OASIS–D data elements to the equivalent OASIS–E data elements for use in the methodology to analyze the difference between assumed versus actual behavior change on estimated aggregate expenditures.

In section II.D. of this proposed rule, we discuss a proposal to recalibrate the CY 2025 home health LUPA thresholds, case-mix weights, and co-morbidity subgroups. Additionally, we discuss providers' suggestions regarding the reassignment of specific ICD–10–CM diagnosis codes under the PDGM.

In section II.E. of this proposed rule, we propose to update the home health wage index and adopt the new labor market delineations from the July 21, 2023, OMB Bulletin No. 23–01 based on data collected from the 2020 Decennial Census. This section includes the CY 2025 national, standardized 30-day period payment rate update, the updated CY 2025 national per-visit payment amounts by the home health payment update percentage, and the OT LUPA add-on factor and PT, SLP, and SN add-on factor updates. The proposed home health payment update percentage for CY 2025 is 2.5 percent. Additionally, this rule proposes the CY 2025 FDL ratio to ensure that aggregate outlier payments are projected not to exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.F.4. of this proposed rule, we propose the CY 2025 payment rate update for dNPWT devices.

2. Home Health Quality Reporting Program (HH QRP)

In section III. of this proposed rule, we are proposing to collect four new items as standardized patient assessment data elements in the social determinants of health (SDOH) category and modify one item collected as a standardized patient assessment data element in the SDOH category beginning with the CY 2027 HH QRP. The four assessment items proposed for collection are: one Living Situation item, two Food items, and one Utilities item. We also propose modifying the current Transportation item beginning with the CY 2027 HH QRP. We are also proposing an update to the removal of the suspension of OASIS all-payer data collection to change all-payer data collection to begin with the start of care OASIS data collection timepoint instead of discharge timepoint. Lastly, we seek input on future HH QRP measure concepts.

3. Expanded Home Health Value Based Purchasing (HHVBP) Model

In section IV. of this proposed rule, we include an RFI related to future measure concepts for the expanded HHVBP Model. We are also including an update to the RFI, *Future Approaches to Health Equity in the Expanded HHVBP Model,* that was published in the CY 2023 HH PPS final rule (87 FR 66874, November 4, 2022) and subsequently updated in the CY 2024 HH PPS final rule (88 FR 77687, November 13, 2023).

4. Home Intravenous Immune Globulin (IVIG) Items and Services

In section V.D.1. of this proposed rule, we propose a rate update for CY 2025 IVIG items and services payment under the home intravenous immune globulin (IVIG) benefit.

5. Home Health CoP Changes

In section VI.A. of this proposed rule, we are proposing to add a new standard at § 484.105(d) that would require HHAs to develop, implement, and maintain an acceptance to service policy that is applied consistently to each prospective patient referred for home health care. We also propose that the policy must address, at minimum, the following criteria related to the HHA's capacity to provide patient care: the anticipated needs of the referred prospective patient, the HHA's case load and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff. We also propose that HHAs would be required to make specified information available to the public that is reviewed at least annually. Section VI.B. of this proposed rule we include an RFI to obtain information from stakeholders on whether CMS should shift its longstanding policy and permit rehabilitative therapists to conduct the initial and comprehensive assessment for cases that have both therapy and nursing services ordered as part of the plan of care. Specifically, we are seeking information regarding the training and education of rehabilitative therapists that is relevant to conducting the initial and comprehensive assessments and any additional information on any patient health and safety benefits or unintended consequences of expanding the category of clinicians that can conduct the initial and comprehensive assessments. In addition, we are seeking public comments on other factors that influence the patient referral and intake processes.

6. Provider and Supplier Enrollment Requirements

Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. We are proposing to expand the definition of ''new provider or supplier'' (solely for purposes of applying a PPEO) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges.

7. Long-Term Care (LTC) Requirements for Acute Respiratory Illness Reporting

The current LTC requirements for reporting COVID–19 related data expire on December 31, 2024, except for reporting COVID–19 resident and staff vaccination status. Given the utility of LTC facility data, we propose to replace these requirements with streamlined continued data reporting requirements for certain respiratory illnesses. We are also proposing additional, related data elements that could be activated in the event of a future acute respiratory illness PHE.

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 2025 HH PPS Payment Rate Update		The overall economic impact related to the changes in payments under the HH PPS for CY 2025 is estimated to be -$280 million (-1.7 percent). The $280 million decrease in estimated payments for CY 2025 reflects the effects of the CY 2025 proposed home health payment update percentage of 2.5 percent ($415 million increase), an estimated 3.6 percent decrease* that reflects the effects of the permanent behavior assumption adjustment ($595 million decrease) and an estimated 0.6 percent decrease that reflects the effects of an updated FDL ($100 million decrease). *The estimated 3.6 percent decrease related to the proposed behavior assumption adjustment includes all payments, while the proposed -4.067 percent BA adjustment only applies to the national, standardized 30-Day period payments and does not impact payments for 30-day periods which are LUPAs.	To ensure that home health payments are consistent with statutory payment authority for CY 2025.
HH QRP		The total economic impact of these proposals including the addition of one Living Situation item, two Food items, and one Utilities item, and the modification of the current Transportation item proposed for implementation in CY 2027 is an estimated increase of $12,604,894.62	Collection of the new SDOH items will also permit us to develop the statistical tools necessary to maximize the value of Medicare data, reducing costs and improving the quality of care for all beneficiaries.
Expanded HHVBP Model		There are no transfers related to the RFI or the HE Update.	The purpose of the RFI and HE updates is to obtain feedback on potential new performance measures and measure concepts for potential future rulemaking.
CY 2025 Home IVIG Items and Services Payment Rate Update		The overall economic impact for CY 2025 is an estimated increase of $9,435,233 in total costs to Medicare FFS.	To update the items and services payment under the home intravenous immune globulin benefit in accordance with section 4134 of the CAA of 2023.

Provision Description	Costs and Cost Savings	Transfers	Benefits
Home Health CoP Changes	To develop, implement, and maintain through an annual review the acceptance to service policy, we expect a one-time cost to develop the policy at a total of $3,078,400 for all HHA's and $ $65,999 for an annual review. To make specified information publicly available, we estimate a onetime cost of $99,763 for all HHA's and $33,286 for an annual update.	No transfers related to this policy.	To improve the referral process and reduce avoidable care delays by helping to ensure that referring entities and patients– can select the most appropriate HHA based on their care needs and to make this information available to the public.
Provider Enrollment Provisions			To strengthen CMS' ability to detect and deter Medicare fraud, waste, and abuse by reactivating providers and suppliers.
Long-Term Care (LTC) Requirements for Acute Respiratory Illness Reporting	To review and update the facility's infection control policies and procedures we estimate a cost of $182 per LTC facility. To electronically report the required data, we estimate costs ranging from $4,732 to $33,215 per LTC facility depending on the required reporting frequency as determined by the Secretary. The low estimate is based on weekly reporting and the high estimate is based on daily reporting. In total, we estimate costs ranging from $4,914 to $33,397 per LTC facility to comply with the proposed requirements.	No transfers related to this policy.	To continue national monitoring of COVID-19, Influenza, and respiratory syncytial virus (RSV) cases to guide infection control interventions and LTC facility operations that directly relate to resident safety; monitor emerging and evolving respiratory illnesses; guide and motivate community-level disease control interventions; and enhance preparedness and resiliency to improve health system responses to future threats, including pandemics that pose catastrophic risks to resident safety and the health care system.

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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 requires 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), we issued a final rule which appeared in the July 3, 2000, **Federal Register** (65 FR 41128) to implement the HH PPS legislation.

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 home health payment update 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 issued 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 annually to 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, section 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.

Division FF, section 4136 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328) amended section 1834(s)(3)(A) of the Act to require that, beginning with 2024, the separate payment for furnishing negative pressure wound therapy (NPWT) be for just the device and not for nursing and therapy services. Payment for nursing and therapy services are to be included as part of payments under the HH PPS. The separate payment for 2024 was required to be equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (as of January 1, 2022) for the applicable disposable device updated by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI–U). The separate payment for 2025 and each subsequent year is to be the payment amount for the previous year updated by the percentage increase in the CPI–U (United States city average) for the 12-month period ending in June of the previous year reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act for such year. The CAA, 2023 also added section 1834(s)(4) of the Act to require that beginning with 2024, as part of submitting claims for the separate payment, the Secretary shall accept and process claims submitted using the type of bill that is most commonly used by home health agencies to bill services under a home health plan of care.

2. Current System for Payment of Home Health Services

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 also part of the national, standardized 30-day period rate. Durable medical equipment (DME) 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. Additionally, the 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and disposable negative pressure wound therapy (dNPWT) devices, but such drugs and devices must be billed by the HHA while a patient is under a home health plan of care, as the law requires consolidated billing of osteoporosis drugs and dNPWT devices.

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 SE20005 available at *https://www.cms.gov/regulations-and-guidanceguidance transmittals2020-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. 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).

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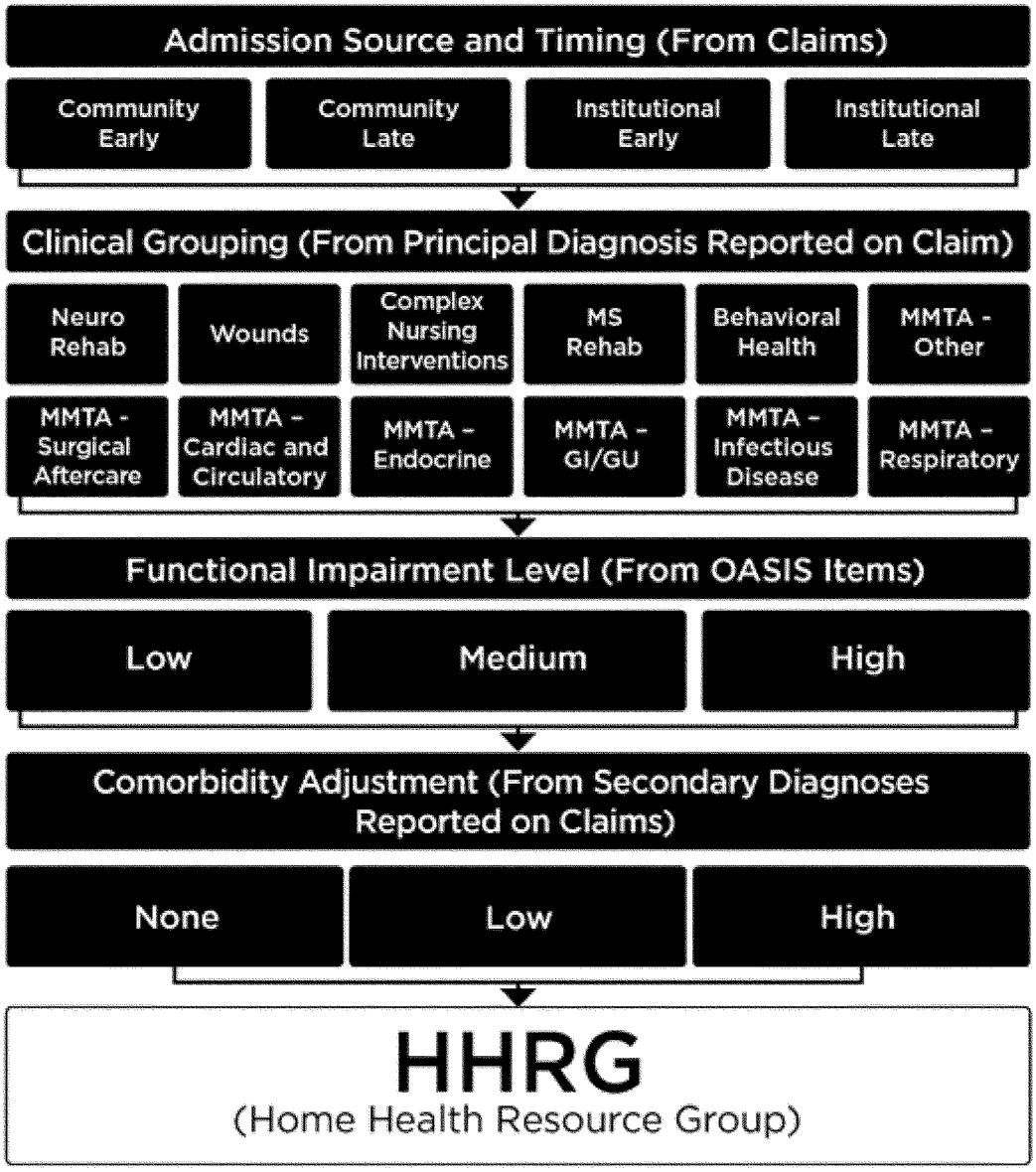
FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



B. Monitoring the Effects of the Implementation of PDGM

1. Routine PDGM Monitoring

CMS routinely analyzes Medicare home health benefit utilization, including but not limited to, overall total 30-day periods of care and average periods of care per HHA user; distribution of the type of visits in a 30-day period of care; the percentage of periods that receive the LUPA; estimated costs; 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, nursing visits, and/or aide/social worker visits. For the monitoring included in this proposed rule, we examine simulated data for CYs 2018 and 2019 and actual data for CYs 2020, 2021, 2022, and 2023 for 30-day periods of care. For CYs 2018 and 2019, because the HH PPS accounted for care in 60-dayepisodes, before the transition to 30-day periods of care beginning in 2020, this actual data was simulated to reflect 30-day periods of care. We refer readers to the CY 2022 HH PPS final rule (86 FR 35881) for further discussion about simulated data for CYs 2018 and 2019. In this proposed rule, we are also including monitoring of home health visits using telecommunications technology and remote patient monitoring, which we began collecting on claims submitted voluntarily beginning January 1, 2023, and which was required beginning July 1, 2023.

a. Utilization

Table 2 shows the overall utilization of home health. The data indicate the average number of 30-day periods of care per unique HHA user is similar per 30-day periods of care between CY 2022 and CY 2023. The data also show a decreasing trend in the overall number of 30-day periods of care between CY 2018 and CY 2023. Table 2 shows utilization of visits per 30-day period of care by home health discipline over time. Table 2 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. The data show a

decreasing trend in the average number of visits per 30-day period and average number of visits per discipline for LUPA 30-day periods of care between CY 2018 and CY 2023.

TABLE 2: OVERALL UTILIZATION OF HOME HEALTH SERVICES, CYs 2018-2023

Volume of Periods and Number of Beneficiaries	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
30-Day Periods of Care	9,336,898	8,744,171	8,423,688	9,269,971	8,593,266	8,133,377
Unique Beneficiaries	2,980,385	2,802,560	2,850,916	3,017,464	2,831,138	2,668,884
Average Number of 30-Day Periods per Unique Beneficiary	3.13	3.12	2.95	3.07	3.04	3.05

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, partial episode payments (PEPs), and outliers).

TABLE 3: UTILIZATION OF VISITS PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE, CYs 2018-2023

Discipline	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Skilled Nursing	4.53	4.49	4.35	4.05	3.90	3.86
Physical Therapy	3.30	3.33	2.70	2.74	2.77	2.78
Occupational Therapy	1.02	1.07	0.79	0.78	0.77	0.76
Speech Therapy	0.21	0.21	0.16	0.15	0.14	0.14
Home Health Aide	0.72	0.67	0.54	0.48	0.43	0.41
Social Worker	0.08	0.08	0.06	0.05	0.05	0.05
Total (all disciplines)	**9.86**	**9.85**	**8.59**	**8.25**	**8.06**	**8.00**

Source: CY 2018 and CY 2019 simulated PDGM data with behavior assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

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 2018-2023

	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Total LUPA % of Overall 30-day Periods	6.7%	6.8%	8.7%	7.9%	7.8%	6.8%
Discipline (Average # visits for LUPA home health periods)						
Skilled Nursing	1.15	1.14	1.19	1.12	1.08	0.99
Physical Therapy	0.43	0.46	0.53	0.55	0.60	0.51
Occupational Therapy	0.07	0.07	0.08	0.08	0.09	0.07
Speech Therapy	0.02	0.02	0.02	0.02	0.02	0.02
Home Health Aide	0.01	0.01	0.01	0.01	0.01	0.01
Social Worker	0.01	0.01	0.01	0.01	0.01	0.01
Total	**1.69**	**1.71**	**1.84**	**1.79**	**1.81**	**1.61**

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.

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

b. Analysis of 2022 Cost Report Data for 30-Day Periods of Care

In the CY 2024 HH PPS proposed rule (88 FR 43664), we provided a summary of analysis on FY 2021 HHA cost report data, as this was the most recent and complete cost report data at the time of rulemaking, and CY 2022 claims to estimate 30-day period of care costs. Our analysis showed that the CY 2022 national, standardized 30-day period payment rate of $2,031.64 was approximately 45 percent more than the estimated CY 2022 estimated 30-day period cost of $1,402.27.

Using this same process in this proposed rule to compare home health payment to costs, we examined 2022 HHA Medicare cost reports, as this is the most recent and complete cost report data at the time of rulemaking, and CY 2023 home health claims, to estimate 30-day period of care costs. We excluded LUPAs and visits with partial episode payments (PEPs) when calculating the average number of visits. The 2022 average NRS costs per visit is $4.38. To update the estimated 30-day period of care costs, we begin with the 2022 average costs per visit with NRS for each discipline and multiply that amount by the CY 2023 home health payment update factor of 1.04. That amount for each discipline is then multiplied by the 2023 average number of visits by discipline to determine the 2023 Estimated 30-day Period Costs. Table 5 shows the estimated average costs for 30-day periods of care by discipline with NRS and the total estimated 30-day period of care costs with NRS for CY 2023.

TABLE 5: ESTIMATED AVERAGE COSTS FOR 30-DAY PERIODS OF CARE IN CY 2023

Discipline	2022 Average Costs per visit with NRS	2023 Market Basket Update Factor	2023 Average Number of Visits	2023 Estimated 30-Day Period Costs
Skilled Nursing	$176.50	1.04	4.08	$748.92
Physical Therapy	$176.71	1.04	2.95	$542.15
Occupational Therapy	$172.48	1.04	0.81	$145.30
Speech Pathology	$200.12	1.04	0.15	$31.22
Medical Social Services	$302.77	1.04	0.05	$15.74
Home Health Aides	$95.94	1.04	0.44	$43.90
Total				**$1,527.23**

Source: 2022 Medicare cost report data obtained on February 1, 2024. Home health visit information came from 30-day periods with a through date in CY2023 (Obtained from the CCW VRDC on March 19, 2024).

The CY 2023 national standardized 30-day period payment rate was $2,010.69, which is approximately 32 percent more than the estimated CY 2023 30-day period average facility cost of $1,527.23. In its March 2024 Report to Congress, MedPAC assumed costs will increase by only 0.55 percent, the average of the increases in costs per 30-day period for 2021 and 2022.[1] Furthermore, MedPAC noted that for more than a decade, payments under the HH PPS have significantly exceeded HHAs' costs. MedPAC also noted an increase of 4.0 percent in the costs per 30-day period for freestanding HHAs in 2022, a reversal of the trend for 2021, where costs per 30-day period decreased by 2.9 percent. This increase in 2022 was due to higher costs per visit, but it was offset by a reduction in the number of in-person visits per 30-day period. As shown in table 5 in this proposed rule, HHAs have reduced visits under the PDGM in CY 2022.

c. 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 a patient is 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.

TABLE 6: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY THE 12 PDGM CLINICAL GROUPS, CYs 2018-2023

Clinical Grouping	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Behavioral Health	1.7%	1.5%	2.3%	2.4%	2.3%	2.2%
Complex Nursing	2.6%	2.5%	3.5%	3.3%	3.2%	3.1%
MMTA – Cardiac	16.5%	16.1%	18.9%	18.5%	17.9%	17.5%
MMTA – Endocrine	17.3%	17.4%	7.2%	6.9%	6.8%	7.0%
MMTA – GI/GU	2.2%	2.3%	4.7%	4.7%	4.9%	5.0%
MMTA – Infectious	2.9%	2.7%	4.8%	4.6%	4.6%	4.7%
MMTA – Other	4.7%	4.7%	3.1%	3.6%	3.5%	3.7%
MMTA – Respiratory	4.3%	4.1%	7.8%	8.0%	7.8%	7.2%
MMTA – Surgical Aftercare	1.8%	1.8%	3.6%	3.4%	3.4%	3.5%
MS Rehab	17.1%	17.3%	19.4%	19.8%	20.8%	21.2%
Neuro Rehab	14.4%	14.5%	10.5%	10.9%	11.0%	10.9%
Wounds	14.5%	15.1%	14.2%	13.9%	13.7%	14.0%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. Analysis of PDGM claims data for CY 2020 through CY 2023. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). 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 of care 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.B.4.c. of this proposed rule and the CY 2020 final rule with comment period (84 FR 60493) for further information on the comorbidity adjustment categories. 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.

[1] Report to Congress, Medicare Payment Policy. Home Health Care Services, Chapter 7. MedPAC. March 2024 (*https://www.medpac.gov/wp-content/uploads/2024/03/Ch7_Mar24_MedPAC_Report_To_Congress_SEC.pdf*).

TABLE 7: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY COMORBIDITY ADJUSTMENT CATEGORY FOR 30-DAY PERIODS, CYs 2018-2023

Comorbidity Adjustment	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
None	55.6%	52.0%	49.1%	49.6%	37.3%	30.7%
Low	35.3%	38.0%	36.9%	36.9%	47.8%	52.6%
High	9.2%	10.0%	14.0%	13.5%	14.9%	16.7%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

d. 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 will be designated as institutional admissions. The institutional admission source category will also include patients that had an acute care hospital stay during a previous 30-day period of care and within 14 days prior to the subsequent, contiguous 30-day period of care and for which the patient was not discharged from home health and readmitted.

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.

TABLE 8: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY ADMISSION SOURCE AND PERIOD TIMING, CYs 2018-2023

Admission Source	Period Timing	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Community	Early	13.5%	13.8%	12.4%	11.6%	11.7%	11.7%
Community	Late	61.1%	60.9%	61.8%	63.7%	63.1%	63.2%
Institutional	Early	18.6%	18.4%	20.0%	18.6%	19.2%	19.2%
Institutional	Late	6.8%	6.9%	5.8%	6.1%	6.0%	6.0%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

e. 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 8 in the CY 2020 HH PPS final rule with comment period (84 FR 60490).[2] 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.[3] The sum of these points results in a functional

[2] CMS continues to use the M1800–1860 items to determine functional impairment level for case mix purposes while we continue to analyze the relationship between the analogous GG items (required as standardized patient assessment data) and the M1800 items used for payment.

[3] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/HH-PDGM.*

impairment 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. A patient's functional impairment level will remain the same for the first and second 30-day periods of care unless there is a significant change in condition that warrants 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 occurrence code 50 on the claim to correspond to the M0090 date of the applicable assessment. Table 9 shows the distribution of 30-day periods by functional impairment level.

TABLE 9: DISTRIBUTION OF 30-DAY PERIODS OF CARE BY FUNCTIONAL IMPAIRMENT LEVEL, CYs 2018-2023

Functional Impairment Level	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Low	33.9%	31.9%	25.7%	23.2%	28.1%	29.8%
Medium	34.9%	35.5%	32.7%	32.6%	33.1%	31.8%
High	31.2%	32.6%	41.7%	44.2%	38.8%	38.3%

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

f. 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. We examined the proportion of actual 30-day periods of care with and without therapy visits. 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.[4] As shown in table 10, we monitor the number of visits per 30-day period 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 visit, and no therapy visits. Figure 2 shows the proportion of 30-day periods of care by the number of therapy visits (excluding zero) provided during 30-day periods of care.

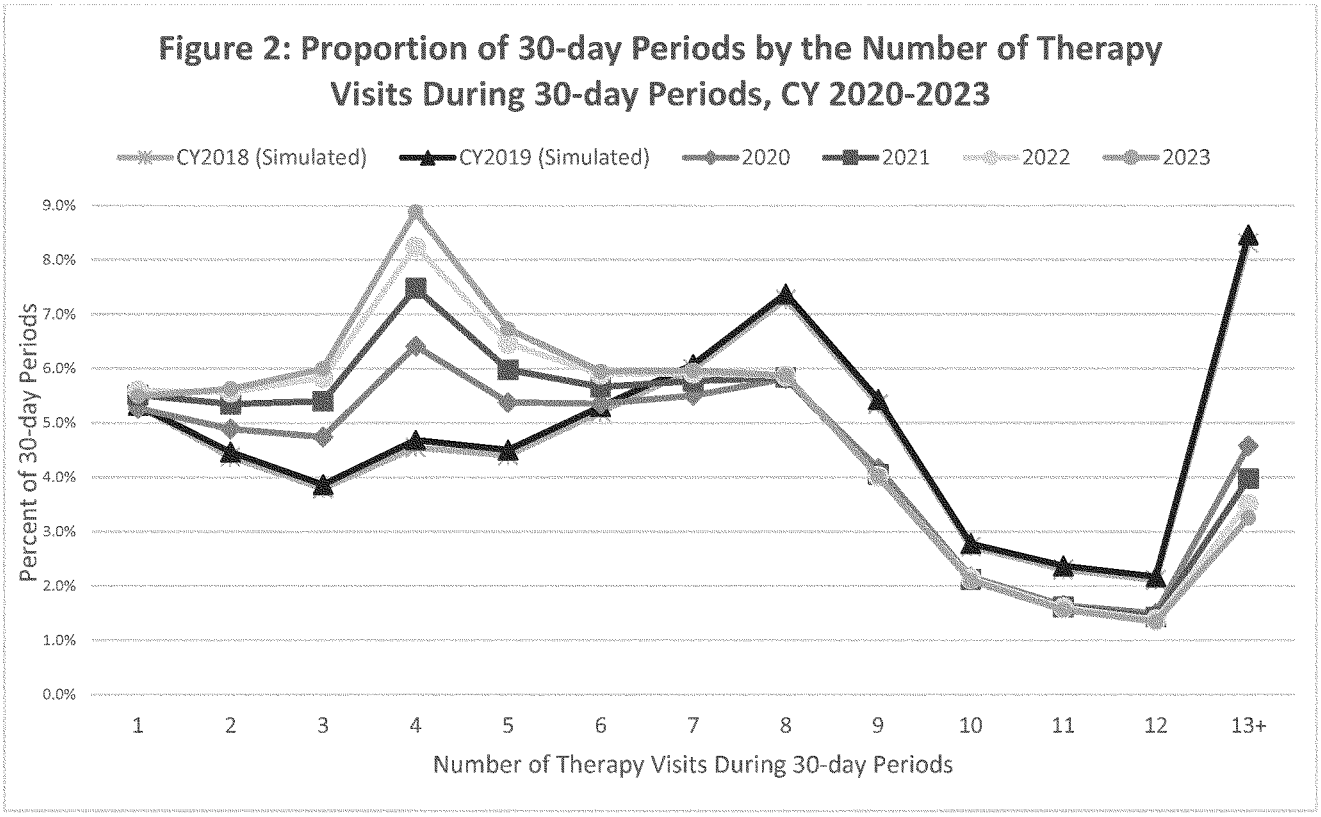
TABLE 10: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY THERAPY, AT LEAST ONE THERAPY VISIT, AND NO THERAPY VISITS FOR CYs 2018-2023

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Therapy Only	13.5%	14.4%	15.2%	17.8%	19.3%	20.1%
Therapy + Non-Therapy	48.2%	48.4%	42.2%	42.3%	42.7%	42.8%
No Therapy	38.3%	37.2%	42.6%	39.9%	38.0%	37.1%
Total 30-day periods	**9,336,898**	**8,744,171**	**8,423,688**	**8,962,690**	**8,593,266**	**8,133,377**

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

[4] 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*).

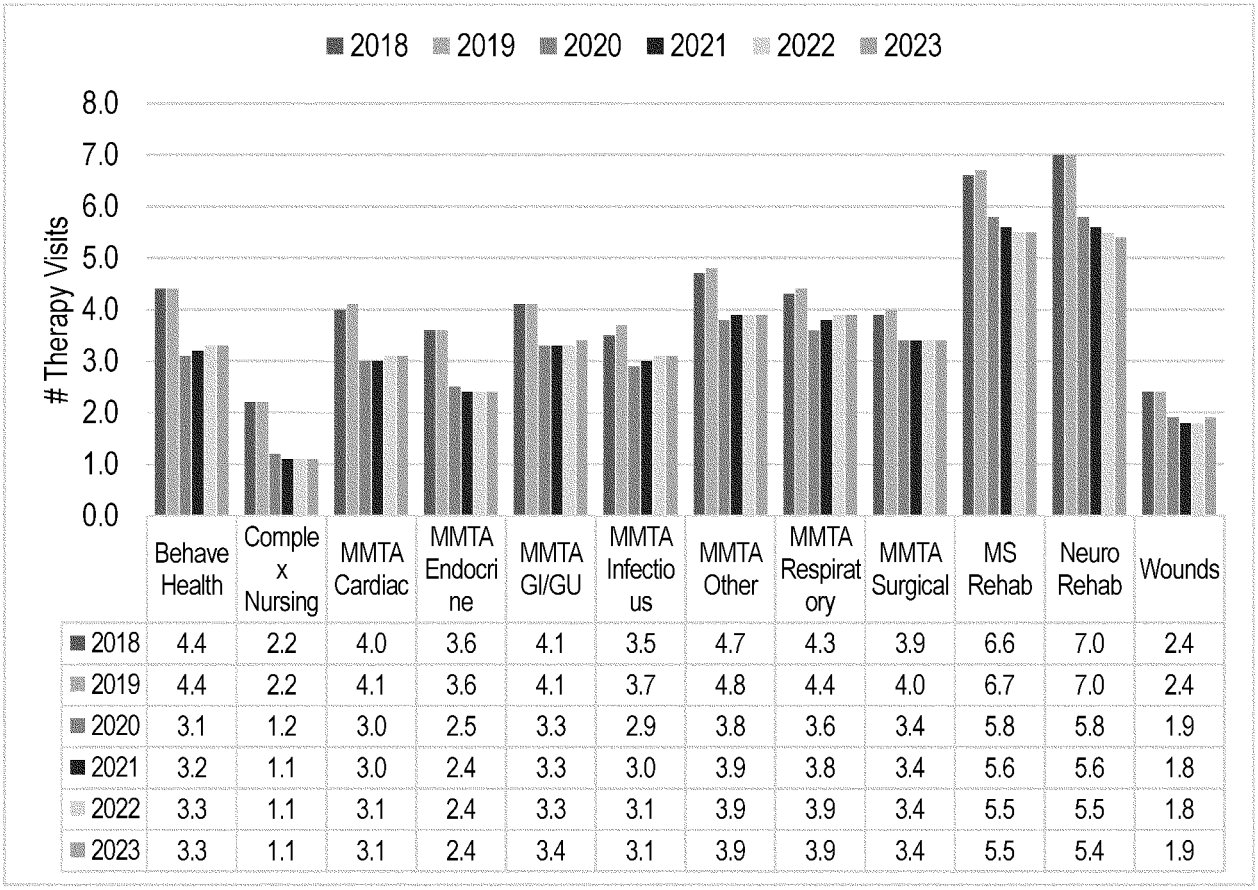
FIGURE 2: PROPORTION OF 30-DAY PERIODS OF CARE BY THE NUMBER OF THERAPY VISITS DURING 30-DAY PERIODS, CYs 2018-2023



Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis. Thirty-day periods with ≥13 therapy visits were combined into one category for illustrative purposes only.

Both table 10 and figure 2, as previously discussed, indicate there have been changes in the distribution of both therapy and non-therapy visits in CY 2023 compared to CY 2022. For example, the percent of 30-day periods with one through seven therapy visits during a 30-day period increased in CY 2023 compared to CY 2022. Comparing therapy utilization from before the PDGM (CYs 2018 and 2019) to after the implementation of the PDGM (CYs 2020–2023), we have also seen a decline in therapy visits across all clinical groups, as shown in figure 2.

TABLE 11: AVERAGE THERAPY VISITS PER 30-DAY PERIOD BY CLINICALGROUP, CYs 2018-2023



	Behave Health	Complex Nursing	MMTA Cardiac	MMTA Endocrine	MMTA GI/GU	MMTA Infectious	MMTA Other	MMTA Respiratory	MMTA Surgical	MS Rehab	Neuro Rehab	Wounds
2018	4.4	2.2	4.0	3.6	4.1	3.5	4.7	4.3	3.9	6.6	7.0	2.4
2019	4.4	2.2	4.1	3.6	4.1	3.7	4.8	4.4	4.0	6.7	7.0	2.4
2020	3.1	1.2	3.0	2.5	3.3	2.9	3.8	3.6	3.4	5.8	5.8	1.9
2021	3.2	1.1	3.0	2.4	3.3	3.0	3.9	3.8	3.4	5.6	5.6	1.8
2022	3.3	1.1	3.1	2.4	3.3	3.1	3.9	3.9	3.4	5.5	5.5	1.8
2023	3.3	1.1	3.1	2.4	3.4	3.1	3.9	3.9	3.4	5.5	5.4	1.9

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.

Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

We also examined the proportion of 30-day periods of care with and without skilled nursing, social work, or home health aide visits. Table 12 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 12 shows the number of 30-day periods of care with and without home health aide and/or social worker visits.

TABLE 12: PROPORTION OF 30-DAY PERIODS OF CARE WITH ONLY SKILLED NURSING, SKILLED NURSING + OTHER VISIT TYPE, AND NO SKILLED NURSING VISITS FOR CYs 2018-2023

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Skilled Nursing Only	33.8%	33.1%	38.5%	36.2%	34.7%	34.1%
Skilled Nursing + Other	51.6%	51.5%	45.3%	44.9%	45.0%	44.7%
No Skilled Nursing	14.7%	15.5%	16.2%	18.9%	20.4%	21.2%
Total 30-day periods	**9,336,898**	**8,744,171**	**8,423,688**	**8,962,690**	**8,593,266**	**8,133,377**

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 PDGM data was accessed from the CCW VRDC on July 12, 2021. CY 2021 PDGM data was accessed from the CCW VRDC on July 14, 2022. CY 2022 PDGM data was accessed from the CCW VRDC on January 20, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

TABLE 13: PROPORTION OF 30-DAY PERIODS OF CARE WITH AND WITHOUT HOME HEALTH AIDE AND/OR SOCIAL WORKER VISITS FOR CYs 2018-2023

30-day Period Visit Type	CY 2018 (Simulated)	CY 2019 (Simulated)	CY 2020	CY 2021	CY 2022	CY 2023
Any HH aide and/or social worker	16.6%	15.9%	13.2%	12.2%	11.3%	10.8%
No HH aide and/or social worker	83.4%	84.1%	86.8%	87.8%	88.7%	89.2%
Total 30-day periods	**9,336,898**	**8,744,171**	**8,423,688**	**8,962,690**	**8,593,266**	**8,133,377**

Source: CY 2018 and CY 2019 simulated PDGM data with behavioral assumptions came from the Home Health LDS. CY 2020 data was accessed from the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC) on July 12, 2021. CY 2021 data was accessed from the CCW VRDC on July 14, 2022. CY 2022 data was accessed from the CCW VRDC on July 13, 2023. CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers). There are approximately 540,000 60-day episodes that started in 2019 and ended in 2020 that are not included in the analysis.

g. Home Health Services Using Telecommunications Technology

As discussed in the CY 2023 final rule (87 FR 66858), we began collecting data on the use of telecommunications technology used during a home health period using three new G-codes reported on home health claims. Collecting data on services furnished via telecommunications technology on claims allows CMS to analyze the characteristics of patients using services provided remotely and have a broader understanding of the social determinants that affect who benefits most from these services, including what barriers may potentially exist for certain subsets of patients. The monitoring discussion illustrates which services are most frequently furnished via telecommunication technology and generally how long remote patient monitoring is utilized.

We began collecting this information from HHAs on January 1, 2023, on a voluntary basis and have required this information to be reported on claims starting on July 1, 2023 (87 FR 66858). The three new G-codes help identify when home health services are furnished using synchronous telemedicine rendered via a real-time two-way audio and video telecommunications system (G320); synchronous telemedicine rendered via telephone or other real-time interactive audio-only telecommunications system (G0321); and the collection of physiologic data digitally stored and/or transmitted by the patient to the home health agency, that is, remote patient monitoring (G0322). We capture the usage and length of remote patient monitoring using the start date of the remote patient monitoring and the number of days of monitoring indicated on the claim. We also looked at the disciplines most often providing remote patient monitoring. We examined the utilization of telecommunications technology device during a home health period and remote patient monitoring by looking at home health claims that included the three G-codes. Tables 14 and 15 shows that the use of telecommunications services reported on CY 2023 home health claims are low (roughly 1 percent of all CY 2023 claims) and are mainly associated with skilled nursing.

TABLE 14: UTILIZATION OF TELECOMMUNICATIONS TECHNOLOGY PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE AS INDICATED BY G0320/G0321, CY 2023

	Claims with at Least 1 Service Using Telecommunication	Number of Services Using Telecommunication	Unique Beneficiaries with at Least 1 Service Using Telecommunication	Unique Providers with at Least 1 Service Using Telecommunication
Skilled Nursing	63,049	128,566	48,450	1,221
PT	13,412	21,614	11,167	523
OT	2,761	3,996	2,336	262
SLP	740	1,176	558	107
Aide	5	6	5	1
MSS	1,812	2,052	1,691	195

Source: CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

TABLE 15: UTILIZATION OF REMOTE MONITORING PER 30-DAY PERIODS OF CARE BY HOME HEALTH DISCIPLINE AS INDICATED BY G0322, CY 2023

	Claims with at Least 1 Day of Remote Patient Monitoring	Number of Remote Patient Monitoring Days	Unique Beneficiaries with at Least 1 Day of Remote Patient Monitoring	Unique Providers with at Least 1 Day of Remote Patient Monitoring
Skilled Nursing	19,084	337,194	11,615	494
PT	380	6,072	296	82
OT	20	188	20	15
SLP	53	966	41	7
Aide	6	123	6	4
MSS	271	4,480	145	2

Source: CY 2023 data was accessed from the CCW VRDC on March 19, 2024.
Note: All 30-day periods of care claims were included (for example LUPAs, PEPs, and outliers).

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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, telecommunications technology used during home health periods, and overall home health payments to determine if refinements to the case-mix adjustment methodology or other policies may be needed in the future.

C. Proposed CY 2025 Payment Adjustments Under the HH PPS

1. Proposed Behavior Assumption Adjustments Under the HH PPS

a. Background

As discussed in section II.A.1. of this proposed rule, starting in CY 2020, the Secretary was statutorily required by section 1895(b)(2)(B) of the Act, to change the unit of payment under the HH PPS from a 60-day episode of care to a 30-day period of care. CMS was also 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. In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior change assumptions which were also described in the CY 2022 and 2023 HH PPS rules (86 FR 35890, 87 FR 37614, and 87 FR 66795 through 66796). In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we included these behavioral change assumptions in the calculation of the 30-day budget neutral payment amount for CY 2020, finalizing a negative 4.36 percent behavior change assumption adjustment (''assumed behaviors''). We did not propose any changes for CYs 2021 and 2022 relating to the behavior assumptions finalized in the CY 2019 HH PPS final rule with comment period, or to the negative 4.36 percent behavior change assumption adjustment, finalized in the CY 2020 HH PPS final rule with comment period.

In the CY 2023 HH PPS final rule (87 FR 66796), we stated, based on our annual monitoring at that time, the three

assumed behavior changes did occur as a result of the implementation of the PDGM and that other behaviors, such as changes in the provision of therapy and changes in functional impairment levels also occurred. We also reminded readers that in the CY 2020 HH PPS final rule with comment period (84 FR 60513) we stated 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 the budget-neutral 30-day payment rate for CY 2020 was established. In the CY 2023 HH PPS final rule (87 FR 66796) we provided supporting evidence that indicated the number of therapy visits declined in CYs 2020 and 2021, as well as a slight decline in therapy visits beginning in CY 2019 after the finalization of the removal of therapy thresholds, but prior to implementation of the PDGM. In section II.B.1. of this proposed rule, our analysis continues to show overall the actual 30-day periods are similar to the simulated 30-day periods and there continues to be a decline in therapy visits, indicating that HHAs changed their behavior to reduce therapy visits. Although the analysis demonstrates evidence of individual behavior changes (for example, in the volume of visits for LUPAs, therapy sessions, etc.), we use the entirety of the behaviors in order to calculate estimated aggregate expenditures. The law instructs us to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been made under the prior system.

Section 4142(a) of the CAA, 2023, required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020–2026. This subsection of the CAA, 2023, also required CMS to provide datasets underlying the simulated 60-day episodes and discuss and provide time for stakeholders to provide input and ask questions on the payment rate development for CY 2023. CMS complied with these requirements by posting online both the supplemental limited data set (LDS) and descriptive files and the description of actual behavior changes that affected CY 2023 payment rate development. Additionally, on March 29, 2023, CMS conducted a webinar entitled *Medicare Home Health Prospective Payment System (HH PPS) Calendar Year (CY) 2023 Behavior Change Recap, 60-Day Episode Construction Overview, and Payment Rate Development.* The webinar was open to the public and discussed the actual behavior changes that occurred upon implementation of the PDGM, our approach used to construct simulated 60-day episodes using 30-day periods, payment rate development for CY 2023, and information on the supplemental data files containing information on the simulated 60-day episodes and actual 30-day periods used in calculating the permanent adjustment to the payment rate. Materials from the webinar, including the presentation and the CY 2023 descriptive statistics from the supplemental LDS files, containing information on the number of simulated 60-day episodes and actual 30-day periods in CY 2021 that were used to construct the permanent adjustment to the payment rate, as well as information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments, can be found on the Home Health Patient-Driven Groupings Model web page at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm.*

b. Method to Annually Determine the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Expenditures

In the CY 2023 HH PPS final rule (87 FR 66804), we finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on estimated aggregate expenditures. In the CY 2024 HH PPS final rule (88 FR 77687 through 77688) we provided an overview of the methodology with detailed instructions for each step. The overall methodology as finalized remains the same for evaluating the impact of behavior changes as required by law; however, due to an update of the Outcome and Assessment Information Set (OASIS) instrument, we need to update two minor technical parts and are proposing to add new assumptions in the first step (creating simulated 60-day episodes from 30-day periods These new assumptions are described in this section.

Section 1895(b)(3)(B)(v) of the Act requires HHAs to report certain quality data. As described in regulation at 42 CFR 484.250(a), this data is required to be reported using the OASIS instrument. Under the prior 153-group system (and the first three years for assessments associated with the PDGM completed prior to CY 2023), HHAs submitted the OASIS–D version. However, OMB approved an updated version of the OASIS instrument, OASIS–E, on November 30, 2022, effective January 1, 2023. Thus, OASIS–E is the current version of the OASIS instrument used. The valid OMB control number for this information collection is 0938–1279.

There are 13 items from the OASIS–D used in the 153-group system that are included in the OASIS–E; however, the responses for these items are now only recorded at the start of care (SOC) or resumption of care (ROC) assessments in the OASIS–E and not at all for follow-up assessments as shown in the following figure 3.

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FIGURE 3: ITEMS ASKED ON SOC/ROC AND NOT FOLLOW-UP ON OASIS-E

SOC/ROC
M1311. Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage
M1322. Current Number of Stage 1 Pressure Injuries Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only, it may appear with persistent blue or purple hues.
M1324. Stage of Most Problematic Unhealed Pressure Ulcer/Injury that is Stageable Excludes pressure ulcer/injury that cannot be staged due to a non-removable dressing/device, coverage of wound bed by slough and/or eschar, or deep tissue injury
M1330. Does this patient have a **Stasis Ulcer?**
M1332. Current Number of Stasis Ulcer(s) that are Observable
M1334. Status of Most Problematic Stasis Ulcer that is Observable
M1340. Does this patient have a **Surgical Wound?**
M1342. Status of Most Problematic Surgical Wound that is Observable
M1400. When is the patient dyspneic or noticeably **Short of Breath?**
M1610. Urinary Incontinence or Urinary Catheter Presence
M1620.Bowel Incontinence Frequency
M1630. Ostomy for Bowel Elimination Does this patient have an ostomy for bowel elimination that (within the last 14 days): a) was related to an inpatient facility stay; or b) necessitated a change in medical or treatment regimen?
M2030. Management of Injectable Medications Patient's current ability to prepare and take all prescribed injectable medications reliably and safely, including administration of correct dosage at the appropriate time/intervals. Excludes IV medications.

Note: We only show the assessment prompt for these 13 items. Each item listed has associated responses which can be found in the OASIS Manual located at https://www.cms.gov/medicare/quality/home-health/oasis-user-manuals.

Three items in the OASIS–E differ slightly from the OASIS–D by incorporating more specific questions and responses than in the OASIS–D. These three items, as shown in figure 4, ask about therapies (M1030), vision (M1200), and the frequency of pain interfering with activity (M1242). Additionally, these three items are only asked at SOC/ROC and not follow-up.

FIGURE 4: OASIS-D ITEMS THAT DIFFER FROM OASIS-E

(M1030) Therapies the patient receives at home: **(Mark all that apply.)**

- ☐ 1 - Intravenous or infusion therapy (excludes TPN)
- ☐ 2 - Parenteral nutrition (TPN or lipids)
- ☐ 3 - Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)
- ☐ 4 - None of the above

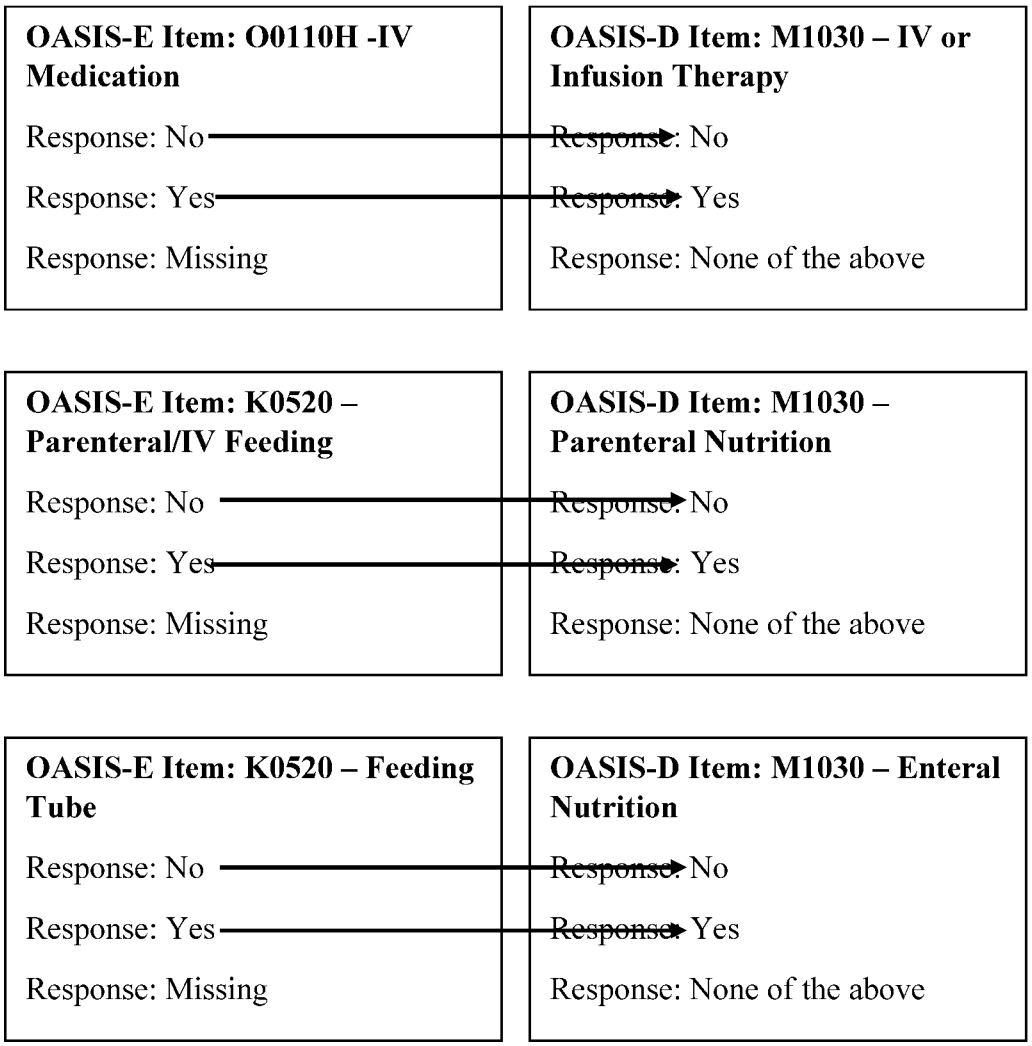
(M1200)	**Vision** (with corrective lenses if the patient usually wears them):
Enter Code ☐	0 Normal vision: sees adequately in most situations; can see medication labels, newsprint. 1 Partially impaired: cannot see medication labels or newsprint, but can see obstacles in path, and the surrounding layout; can count fingers at arm's length. 2 Severely impaired: cannot locate objects without hearing or touching them, or patient nonresponsive.
(M1242)	**Frequency of Pain Interfering** with patient's activity or movement:
Enter Code ☐	0 Patient has no pain 1 Patient has pain that does not interfere with activity or movement 2 Less often than daily 3 Daily, but not constantly 4 All of the time

The differences in these three items from what is included in OASIS–E necessitate a mapping methodology to impute the OASIS–D responses using OASIS–E to create simulated 60-day episodes under the 153-group case mix system from 30-day periods under the PDGM. For each of the three items, we considered the clinical relationship between the responses in the OASIS–E items that differ from the OASIS–D items. CMS also considered the response distribution between the OASIS–D and OASIS–E items when creating the mapping of the responses.

CMS believes the following two proposals on assumptions are the most appropriate to address the changes from the OASIS–D to the OASIS–E to continue to create simulated 60-day episodes from 30-day periods.

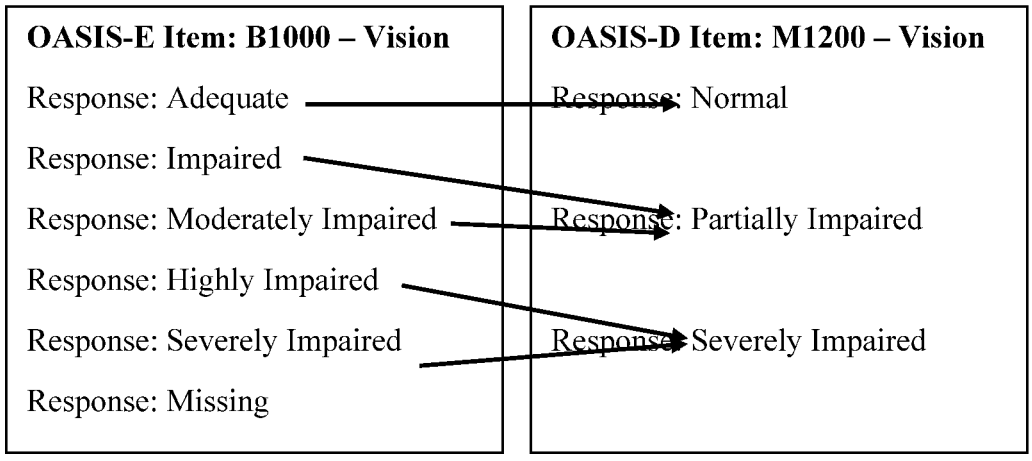
- If the simulated 60-day episode matches to a SOC or ROC assessment then we are proposing not to impute the 13 items. If the simulated 60-day episode matches to a follow-up assessment, then we are proposing to look back for the most recent 30-day period that is linked to a SOC or ROC assessment and impute the 13 responses for follow-up using the responses at the most recent SOC or ROC assessment. We would limit the look back period to the beginning of the calendar year that precedes the calendar year for the claim. For example, a simulated 60-day episode with a follow-up assessment on June 1, 2023, would have a look-back period for a 30-day period linked to a SOC or ROC assessment that began on or after January 1, 2022. If we cannot find a SOC or ROC assessment in that time period, we are proposing to exclude the claim from analysis because we would not have sufficient timely data to impute responses.
- If the simulated 60-day episode matches to an OASIS–D assessment, then we are proposing to use the OASIS–D for responses. If the simulated 60-day episode matches to an OASIS–E assessment, we are proposing to apply the following mapping for the therapies, vision, and pain items to impute responses as these responses are required for accurate payment calculation under the prior 153-group system. We are also proposing to apply the look-back period as described in the assumption earlier when necessary.

FIGURE 5: THERAPIES MAPPING FROM OASIS-E TO OASIS-D



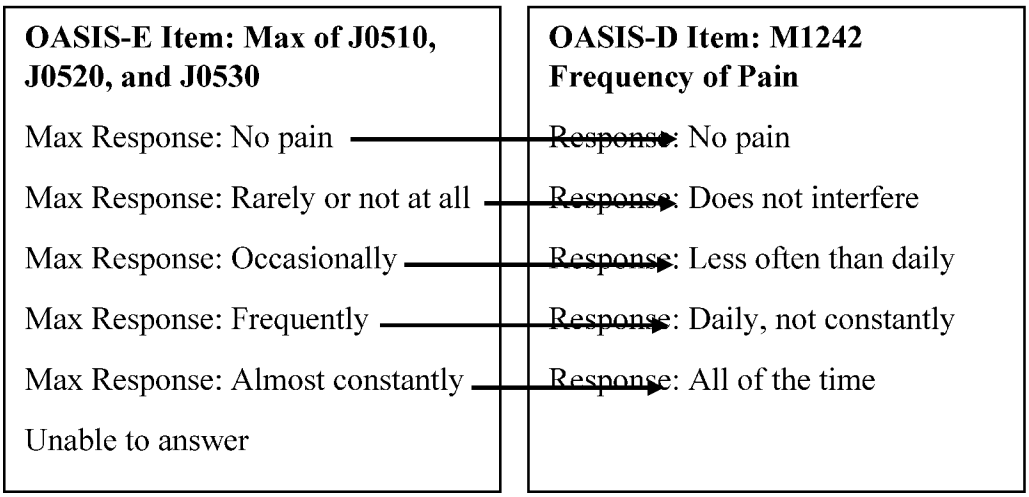
Note, if an OASIS–E assessment has a response of ''no'' to all three items (O0110H—IV medication, K0520—Parenteral/IV feeding, and K0520—Feeding Tube), as shown in figure 5, then the mapping for M1030 would be a response of ''none of the above''.

FIGURE 6: VISION MAPPING FROM OASIS-E TO OASIS-D



On the OASIS–D there was one pain item (M1242—Frequency of Pain Interfering with patient's activity or movement) used for payment policy. There are three pain related items on the OASIS–E (J0510—pain effect on sleep, J0520—pain interference with therapy activities, and J0530—pain interference with day-to-day activities) that correspond to the one OASIS–D pain item used for calculating payments. Therefore, we believe using the response from J0510, J0520, or J0530 that reflects the maximum severity would be the most appropriate for mapping back to the OASIS–D. For example, if J0510 (pain effect on sleep) has a response of ''rarely'', J0520 (pain interference with therapy activities) has a response of ''frequently'', and J0530 has a response of ''occasionally'', then we would use the response from J0520 (''frequently'') for mapping as this is the most severe response. Figure 7 shows the proposed mapping based on the maximum severity response for any of the three pain items.

FIGURE 7: PAIN MAPPING FROM OASIS-E to OASIS-D



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As this overall methodology was previously finalized in the CY 2023 HH PPS final rule (87 FR 66804) and we are just proposing technical updates based on the updated OASIS instrument, CMS will continue to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been made under the prior system for assessing behavior changes as required by law. We refer readers to the CY 2024 HH PPS final rule (88 FR 77687 through 77688) for an overview of the methodology with detailed instructions for each step. We are soliciting comments on these new proposed assumptions related to mapping of the OASIS–E items.

c. Calculating Permanent and Temporary Payment Adjustments

To offset prospectively for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes, in any given year, we calculate a permanent prospective adjustment by calculating the percent change between the actual 30-day base payment rate and the recalculated 30-day base payment rate. This percent change is converted into an adjustment factor and applied in the annual rate update process.

To offset retrospectively for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes in any given year, we calculate a temporary prospective adjustment by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for the same year. In other words, when determining the temporary retrospective dollar amount, we use the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. In accordance with section 1895(b)(3)(D)(iii) of the Act, the temporary adjustment is to be applied on a prospective basis and shall apply only with respect to the year for which such temporary increase or decrease is made. Therefore, after we determine the dollar amount to be reconciled in any given year, we calculate a temporary adjustment factor to be applied to the base payment rate for that year. The temporary adjustment factor is based on an estimated number of 30-day periods in the next year using historical data trends, and as applicable, we control for a permanent adjustment factor, case-mix weight recalibration neutrality factor, wage index budget neutrality factor, and the home health payment update. The temporary adjustment factor is applied last. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis for CYs 2020 through 2022 claims. Additionally, at the end of this section we provide a summary table for the permanent adjustment and temporary dollar amounts calculated for each year.

d. CY 2023 Preliminary Claims Results

We will continue the practice of using the most recent complete home health claims data available at the time of rulemaking. While the CY 2023 analysis presented in this proposed rule is the most complete data available at the time of this proposed rule, it is considered preliminary and, as more data become available from the latter half of CY 2023, we will update our results in the final rule. The CY 2025 final rule will utilize the CY 2023 finalized data for determining any permanent adjustment needed to the CY 2025 payment rate. However, while the claims data and the

permanent and temporary adjustment results will be considered complete, any adjustments to future payment rates may be subject to additional considerations such as permanent adjustments taken in previous years.

The claims data used in rulemaking is released twice each year in the HH PPS Limited Data Set (LDS) file, one for the proposed and one for the final. Accordingly, the HH PPS LDS file released with this proposed rule includes two files: the actual CY 2023 30-day periods and the CY 2023 simulated 60-day episodes.

We remind readers a data use agreement (DUA) is required to purchase the CY 2025 proposed HH PPS LDS file. Access will be granted for both the 30-day periods and the simulated 60-day episodes under one DUA. Visit the HH PPS LDS web page for more information.[5] In addition, the proposed CY 2025 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH PPS Regulations and Notices webpage,[6] does not require a DUA, and is available at no cost to interested parties. The spreadsheet contains information on the number of simulated 60-day episodes and actual 30-day periods in CY 2023 that were used to determine the adjustments. The spreadsheet also provides information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments.

e. Applying the Methodology to CY 2023 Data To Determine the CY 2025 Permanent and Temporary Adjustments

Using the methodology finalized in the CY 2023 HH PPS final rule and described most recently in the CY 2024 HH PPS final rule (88 FR 77687 through 77688), as well as the two new assumptions related to the OASIS–E mapping, we simulated 60-day episodes using actual CY 2023 30-day periods to determine what the permanent and temporary payment adjustments should be to offset for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes.

Using the preliminary CY 2023 dataset, we began with 8,133,377 30-day periods of care and dropped 452,253 30-day periods of care that had claim occurrence code 50 date after October 31, 2023. We also excluded 866,293 30-day periods of care that had claim occurrence code 50 date before January 1, 2023, to ensure the 30-day period would not be part of a simulated 60-day episode that began in CY 2022. Applying the additional exclusions and assumptions as described in the finalized methodology (87 FR 66804), an additional 12,906 30-day periods were excluded.

Additionally, we excluded 166,441 simulated 60-day episodes of care where no OASIS information was available in the CCW VRDC, a recent SOC/ROC OASIS was not available, or the episode could not be grouped to a HIPPS due to a missing primary diagnosis or other reason. Our simulated 60-day episodes of care produced a distribution of two 30-day periods of care (68.9 percent) and single 30-day periods of care (31.1 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 for this proposed rule included 6,494,947 actual 30-day periods of care and 3,845,954 simulated 60-day episodes of care for CY 2023.

Using the preliminary dataset for CY 2023 (6,494,947 actual 30-day periods which made up the 3,845,954 simulated 60-day episodes) we determined the estimated aggregate expenditures under the pre-PDGM HH PPS were lower than the actual estimated aggregate expenditures under the PDGM HH PPS. This indicates that aggregate expenditures under the PDGM were higher than if the 153-group payment system was still in place in CY 2023 and therefore, we determined the CY 2023 30-day base payment rate should have been $1,873.17 based on actual behavior, as shown in table 16 As stated in the CY 2024 final rule (88 FR 77693) we determined for CYs 2020 through CY 2022 a total of −5.779 percent permanent adjustment was needed (after accounting for the −3.925 percent applied to the CY 2023 payment rate). In order to determine behavior changes for only CY 2023, we simulated what the CY 2023 base payment rate would have been if the full −5.779 percent adjustment that we determined using CY 2022 claims data had been implemented.

Using the recalculated CY 2022 base payment rate of $1,839.10 (88 FR 77693), multiplied by the CY 2023 case-mix weights recalibration neutrality factor (0.9904), the CY 2023 wage index budget neutrality factor (1.0001) and the CY 2023 home health payment update factor (1.040), the CY 2023 base payment rate for assumed behavior would have been $1,894.49. For the CY 2023 annual permanent adjustment, we calculated the percent change between the two payment rates for only CY 2023 (assuming the −5.779 percent adjustment was already taken). For the temporary adjustment we calculated the difference in aggregate expenditures in dollars for all CY 2023 PDGM 30-day claims using the actual payment rate ($2,010.69) and recalculated payment ($1,873.17). This difference is shown as the retrospective dollar amount needed to offset payment in a future year. Our results for the CY 2023 annual (single year) permanent and temporary adjustment calculations using CY 2023 preliminary claims data are shown in table 16.

[5] *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.*

[6] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.*

TABLE 16: CY 2023 PROPOSED PERMANENT AND TEMPORARY ADJUSTMENT CALCULATIONS

	Budget-neutral 30-day Payment Rate with Assumed Behavior Changes	Budget-neutral 30-day Payment Rate with Actual Behavior Changes	CY 2023 Only Adjustment
Base Payment Rate	$1,894.49*	$1,873.17	**Permanent** -1.125%
Aggregate Expenditures	$15,982,282,880*	$15,016,399,156	**Temporary** -$965,883,723

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW March 19, 2024
Notes: *The $1,894.49 is equal to the recalculated budget neutral 30-day base payment rate of $1,839.10 for CY 2022 (shown in table 16) multiplied by the CY 2023 recalibration factor (0.9904), wage index budget neutrality factor (1.0001) and the CY 2023 home health payment update (1.040).
**The estimated aggregate expenditures for assumed behavior ($16 billion), uses the actual CY 2023 payment rate of $2,010.69 as this is what CMS actually paid in CY 2023.

As shown in table 16, a permanent prospective adjustment of −1.125 percent to the CY 2025 30-day payment rate (assuming the −5.779 percent adjustment was already taken) for CY 2023 would be required to offset for such increases in estimated aggregate expenditures in future years. To illustrate this calculation:

$$\frac{(\$1{,}873.17 - \$1{,}894.49)}{|\$1{,}894.49|} = -1.125\ \%$$

Additionally, we determined that our initial estimate of the base payment rate ($2,010.69) resulted in excess expenditures of approximately $966 million in CY 2023. This would require a temporary adjustment, where the dollar amount ($966 million) would be converted to a factor when implemented, to offset for such increases in estimated aggregate expenditures for CY 2023.

f. Proposed CY 2025 Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we describe how we annually analyzed CY 2023 preliminary data to determine the effects of actual behavior change on estimated aggregate expenditures. Again, that analysis included simulations that assumed that the full payment adjustment (−5.779 percent) was already taken. We note that CMS did not implement the full payment adjustment, so the calculations set forth later in this section reflect the lagging adjustments that are still needed.

That is, the calculation in this section includes any of the remaining adjustments not applied in previous years (that is, CYs 2020 to 2022), as well as the adjustment needed to account for CY 2023 claims. In calculating the full permanent adjustment needed to the CY 2025 30-day payment rate, we compare estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 16, we do not assume the full adjustment from prior years had been taken.

As discussed in section II.C.1.d. of this proposed rule, using the preliminary dataset for CY 2023 (6,494,947 actual 30-day periods which made up the 3,845,954 simulated 60-day episodes) we determined the CY 2023 30-day base payment rate should have been $1,873.17 based on actual behavior, rather than the actual CY 2023 30-day base payment rate ($2,010.69) based on assumed behaviors. The percent change, as shown in table 17, between the actual CY 2023 base payment rate of $2,010.69 (based on assumed behaviors and included a −3.925 percent adjustment applied to the CY 2023 payment rate) and the CY 2023 recalculated base payment rate of $1,873.17 (based on actual behaviors) is the total permanent adjustment need for CYs 2020 through 2023.

TABLE 17: TOTAL PERMANENT ADJUSTMENT FOR CYs 2020, 2021, 2022, and 2023

Actual CY 2023 Base Payment Rate (Assumed Behavior)	Recalculated CY 2023 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
$2,010.69	$1,873.17	-6.839%*

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW March 19, 2024.
*This is the total permanent adjustment based on CY 2023 data which includes the previous permanent adjustment of -3.925% applied. However, as described later, we recognize for CY 2025 we must account for adjustment made in CY 2024.

As shown in table 17, a permanent prospective adjustment of −6.839 percent to the CY 2025 30-day payment rate for CYs 2020 through 2023 would be required to offset for such increases in estimated aggregate expenditures in future years. To illustrate this calculation:

$$\frac{(\$1{,}873.17 - \$2{,}010.69)}{|\$2{,}010.69|} = -6.839\ \%$$

As we stated in the CY 2024 HH PPS final rule (88 FR 77697), applying a −2.890 percent permanent adjustment to the CY 2024 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures in CYs 2020, 2021, and 2022. Using CY 2023 claims data, as shown in table 17, a permanent prospective adjustment of −6.839 percent to the CY 2025 30-day payment rate would be required to offset for such increases in estimated aggregate expenditures for CYs 2020 through 2023. We remind readers adjustment factors are multiplied in this payment system and therefore, individual numbers (that is, percentages) cannot be added or subtracted together to determine the final adjustment. Therefore, we cannot determine the CY 2025 proposed permanent adjustment, which would include estimated aggregate expenditures in CY 2023, by simply subtracting the −2.890 percent applied in CY 2024 from the total permanent adjustment of −6.839 percent.

Instead, we account for the permanent adjustment applied in CY 2024 of −2.890 percent when we calculate the CY 2025 permanent adjustment by solving the following equation $(1-0.0289)\times(1-\chi) = (1-0.06839)$. To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1-0.06839}{1-0.0289}\right)$$
$$x = 1 - 0.95933$$
$$x = 0.04067$$

We are required by law [7] to annually analyze data from CY 2020 through CY 2026 and offset any increases or decreases in estimated aggregate expenditures at a time and manner determined appropriate. We now have 4 years of claims data under the PDGM, as well as 1 year with a partial permanent adjustment applied. In previous years' rules, we provided the permanent adjustment calculated for each discrete year of claims.

Permanent Adjustments Calculated:

CY 2020 Claims = −6.52% (87 FR 66805)

CY 2021 Claims = −1.42% (87 FR 66806)

CY 2022 Claims = −1.767% (88 FR 77692)

CY 2023 Claims = −1.125% (Table 16)

Permanent Adjustments Applied:

CY 2023 Rate = −3.925% (88 FR 66808)

CY 2024 Rate = 2.890% (88 FR 77697)

Accounting for the previous permanent adjustments applied to the 30-day payment rate in CYs 2023 and 2024, we can simulate the permanent adjustment calculation with the simulated annual permanent adjustment percentage shown previously for CY 2025:

$(1-0.0652)(1-0.0142)(1-0.01767)(1-0.01125) = (1-0.03925)(1-0.0289)(1-x)$.

Solving, x = 4.067%.

In table 18 we provide the base payment rate for assumed behaviors (simulates all prior adjustments were taken), the recalculated base payment rate for actual behaviors, the annual permanent adjustments calculated (assuming prior adjustments had been taken), the cumulative permanent adjustments calculated in each year, the final permanent adjustments implemented in rulemaking, and the temporary adjustment dollar amount based on actual payment rates.

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[7] Sections 1895(b)(3)(D)(i) and 1895(b)(3)(D)(ii) of the Act.

TABLE 18: SUMMARY OF PERMANENT ADJUSTMENTS FOR CYS 2020 – 2026

Claims Analysis Year	Base Payment Rate for Assumed Behaviors (Actual Amount Paid to HHAs in the Claims Analysis Year)	Base Payment Rate that Reflects Actual Behavior Changes (As Determined After Later Claims Analysis)	Total Permanent Adjustment Between Assumed and Actual Behavior Rates*	Permanent Adjustment CMS Finalized and Implemented in Rulemaking
CY 2020	$1,864.03	$1,742.52	-6.52%	n/a
CY 2021	$1,901.12	$1,751.90	-7.85%	-3.925% applied to CY 2023 rates
CY 2022	$2,031.64	$1,839.10	-5.78%	-2.890% applied to CY 2024 rates
CY 2023	$2,010.69	$1,873.17	Proposed -4.067%	-4.067% proposed to be applied to CY 2025 rates
CY 2024	$2,038.13	TBD	TBD	TBD
CY 2025	TBD	TBD	TBD	TBD
CY 2026	TBD	TBD	TBD	TBD

Notes: With the prospective payment systems, the claims data analyzed differ from the rulemaking cycle. For example, CY 2020 claims are used in CY 2022 rulemaking.

*The total permanent adjustment accounts for prior adjustments that were finalized and implemented through rulemaking.

TABLE 19: SUMMARY OF ANTICIPATED TEMPORARY ADJUSTMENTS CALCULATED FOR CYs 2020 – 2026

Claims Analysis Year	Dollar Amount
CY 2020	-$873,073,121
CY 2021	-$1,211,002,953
CY 2022	-$1,405,447,290
CY 2023 (as of proposed rule)	-$965,883,723
CY 2024	TBD
CY 2025	TBD
CY 2026	TBD
Total	-$4,455,407,087

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed on the CCW July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on CCW July 15, 2023. CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on CCW March 19, 2024.

Note: The anticipated temporary adjustments of approximately $4.5 billion would require temporary adjustment(s) to offset for such increases in estimated aggregate expenditures. The dollar amount would be converted to a factor when implemented in future rulemaking.

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In both the CY 2023 and 2024 final rules (87 FR 66790, 88 FR 77696), we acknowledged that the full permanent adjustment may be burdensome for some providers. In those final rules, we finalized only half of the permanent adjustment percentages (−3.925 percent in CY 2023 and −2.890 percent in CY 2024). However, in this proposed rule, we are proposing to apply the full current remaining permanent adjustment of −4.067 percent in CY 2025, as this would satisfy the statutory requirements at section 1895(b)(3)(D) of the Act to offset any increases or decreases on the impact of differences between assumed behavior and actual behavior changes on estimated aggregate expenditures, reduce the need for any future large permanent adjustments, and help slow the accrual of the temporary payment adjustment amount. In addition, we explained in the CY 2023 HH PPS final rule (87 FR 66808) and the CY 2024 HH PPS final rule (88 FR 77697) that when we applied a reduced permanent adjustment in CY 2023 and CY 2024, that we would need to continue to implement a reduction in future years to satisfy the statutory requirements. Therefore, we believe that CMS has been clear through notice and

comment rulemaking that the remainder of these permanent adjustments would be applied, thereby giving HHAs adequate notice to prepare for this year's proposed rate reduction. Accordingly, we are proposing to apply the full remaining permanent adjustment of −4.067 percent to the CY 2025 home health base payment rate, noting that we will update this percentage using more complete claims data in the final rule.

We stated in the CY 2023 HH PPS final rule (87 FR 66804), the CY 2024 HH PPS proposed rule (88 FR 43674) and in this proposed rule, that after we determine the total dollar amount to be reconciled, we will calculate a temporary adjustment factor to be applied to the base payment rate for the year in which it is implemented. That is, the temporary adjustment dollar amount (currently estimated at $4.5 billion) will be converted to a factor to be applied to the payment rate in a time and manner determined appropriate. As we noted in the CY 2023 HH PPS proposed rule (87 FR 37682) and CY 2024 HH PPS proposed rule (88 FR 43678), we recognize that implementing both the permanent and temporary adjustments in the same year may adversely affect HHAs. Given that the magnitude of both the temporary and permanent adjustments together for CY 2025 rate setting may result in a significant reduction of the payment rate, we are not proposing to take the temporary adjustment in CY 2025. In future year rulemaking, we will propose a temporary adjustment factor to the national, standardized base payment rate in a time and manner determined appropriate. As noted previously, we will update these permanent and temporary adjustments in the final rule to reflect more complete claims data for CY 2023. We solicit comments on the proposal to apply a −4.067 percent permanent adjustment to the CY 2025 base payment rate.

D. Proposed CY 2025 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, Case-Mix Weights, and Reassignment of Specific ICD–10–CM Codes Under the PDGM

1. Proposed CY 2025 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 with comment period (83 FR 56492), we finalized a policy setting the LUPA thresholds at the 10th percentile of visits or two visits, whichever is higher, for each payment group. This means 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 partial payment adjustment 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 per-visit payment amounts as described in section II.C.4.f.2 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 fewer 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, as CY 2020 was the first year of the new case-mix adjustment methodology, we stated in the CY 2021 HH PPS final rule (85 FR 70305, 70306) that 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. We stated that at that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

In the CY 2022 HH PPS final rule with comment period (86 FR 62249), we finalized the proposal to recalibrate the PDGM case-mix weights, functional impairment levels, and comorbidity subgroups while maintaining the LUPA thresholds for CY 2022. We stated that because 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, we believe the COVID–19 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 COVID–19 PHE. We noted that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID–19 PHE, we finalized the proposal 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.

For CY 2024, we proposed to update the LUPA thresholds using CY 2022 Medicare home health claims (as of March 17, 2023) linked to OASIS assessment data. We believed that CY 2022 data will be more indicative of visit patterns in CY 2024 rather than continuing to use the LUPA thresholds derived from the CY 2018 data pre-PDGM. Therefore, we finalized a policy to update the LUPA thresholds for CY 2024 using data from CY 2022.

For CY 2025, we are proposing to update the LUPA thresholds using CY 2023 home health claims utilization data (as of March 19, 2024), in accordance with our policy to annually recalibrate the case-mix weights and update the LUPA thresholds, functional impairment levels and comorbidity subgroups. After reviewing the CY 2023 home health claims utilization data, we determined that LUPA visit patterns in 2023 were similar to visits in 2021. The proposed LUPA thresholds for the CY 2025 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in table 20. We solicit public comments on the proposed updates to the LUPA thresholds for CY 2025. The proposed LUPA thresholds will be updated based on more complete CY 2023 claims data in the final rule.

2. Proposed CY 2025 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 M1033. 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 these points results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the more the response is associated with increased resource use, or increased impairment. The three functional impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each clinical group falls 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 2025, we propose to use CY 2023 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 technical report from December 2016, posted on the Home Health PPS Archive web page located at: *https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive,* provides a more detailed explanation as to the construction of these functional impairment levels using the OASIS items. We are proposing to use the same methodology previously finalized to update the functional impairment levels for CY 2025. The updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2025 are listed in tables 20 and 21, respectively. We solicit public comments on the updates to functional points and the functional impairment levels by clinical group.

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TABLE 20: PROPOSED OASIS POINTS TABLE FOR CY 2025

	Responses	Points (2023)	Percent of Periods in 2023 with this Response Category
M1800: Grooming	0 or 1	**0**	**25.4%**
	2 or 3	**3**	**74.6%**
M1810: Current Ability to Dress Upper Body	0 or 1	**0**	**19.5%**
	2 or 3	**5**	**80.5%**
M1820: Current Ability to Dress Lower Body	0 or 1	**0**	**9.3%**
	2	**3**	**65.3%**
	3	**11**	**25.4%**
M1830: Bathing	0 or 1	**0**	**2.3%**
	2	**3**	**10.0%**
	3 or 4	**10**	**49.6%**
	5 or 6	**18**	**38.0%**
M1840: Toilet Transferring	0 or 1	**0**	**61.0%**
	2, 3 or 4	**5**	**39.0%**
M1850: Transferring	0	**0**	**1.2%**
	1	**1**	**18.8%**
	2, 3, 4 or 5	**4**	**80.0%**
M1860: Ambulation/Locomotion	0 or 1	**0**	**3.1%**
	2	**6**	**13.8%**
	3	**2**	**65.2%**
	4, 5 or 6	**18**	**17.8%**
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	**0**	**58.9%**
	Four or more items marked (Excluding responses 8, 9 or 10)	**12**	**41.1%**

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed from the CCW on March 19, 2024.
Note: For item M1860, the point values for response 2 is worth more than the point values for response 3. There may be times in which the resource use for certain OASIS items associated with functional impairment will result in a seemingly inverse relationship to the response reported. However, this is the result of the direct association between the responses reported on the OASIS items and actual resource use.

TABLE 21: PROPOSED THRESHOLDS FOR FUNCTIONAL LEVELS BY CLINICAL GROUP, FOR CY 2025

Clinical Group	Level of Impairment	Points (2023)
MMTA – Other	Low	**0-28**
	Medium	**29-43**
	High	**44+**
Behavioral Health	Low	**0-28**
	Medium	**29-44**
	High	**45+**
Complex Nursing Interventions	Low	**0-29**
	Medium	**30-52**
	High	**53+**
Musculoskeletal Rehabilitation	Low	**0-29**
	Medium	**30-43**
	High	**44+**
Neuro Rehabilitation	Low	**0-33**
	Medium	**34-49**
	High	**50+**
Wound	Low	**0-32**
	Medium	**33-48**
	High	**49+**
MMTA - Surgical Aftercare	Low	**0-27**
	Medium	**28-40**
	High	**41+**
MMTA - Cardiac and Circulatory	Low	**0-27**
	Medium	**28-40**
	High	**41+**
MMTA – Endocrine	Low	**0-27**
	Medium	**28-40**
	High	**41+**
MMTA - Gastrointestinal tract and Genitourinary system	Low	**0-32**
	Medium	**33-47**
	High	**48+**
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	**0-31**
	Medium	**32-44**
	High	**45+**
MMTA – Respiratory	Low	**0-32**
	Medium	**33-44**
	High	**45+**

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed from the CCW on March 19, 2024.

3. Proposed CY 2025 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:

- *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 when they are reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or do not 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 2025, we propose to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2023 home health data with linked OASIS data (as of March 19, 2024).

For CY 2025, we propose to update the comorbidity subgroups to include 22 low comorbidity adjustment subgroups as identified in table 22 and 90 high comorbidity adjustment interaction subgroups as identified in table 23. The proposed CY 2025 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 2025.

TABLE 22: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2025

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 10	Varicose Veins and Lymphedema
Circulatory 2	Hemolytic, Aplastic, and Other Anemias
Circulatory 9	Other Venous Embolism and Thrombosis
Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Gastrointestinal 2	Intestinal Obstruction and Ileus
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Neoplasms 1	Malignant Neoplasms of Lip, Oral Cavity and Pharynx, includes Head and Neck Cancers
Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neoplasms 20	Non-Hodgkin's Lymphoma
Neurological 10	Diabetes with neuropathy
Neurological 11	Disease of the Macula and Blindness/Low Vision
Neurological 12	Nondiabetic neuropathy
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2022 accessed on the CCW March 19, 2024.

TABLE 23: HIGH COMORBIDITY ADJUSTMENT INTERACTIONS FOR CY 2025

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
1	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Circulatory 10	Varicose Veins and Lymphedema
2	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
4	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
5	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
6	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
7	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
8	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
9	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
10	Behavioral 5	Phobias, Other Anxiety and Obsessive Compulsive Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
11	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension
12	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Circulatory 9	Other Venous Embolism and Thrombosis
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with neuropathy
16	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 12	Nondiabetic neuropathy
17	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Respiratory 2	Whooping cough
18	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
19	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
20	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
21	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
22	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
23	Circulatory 10	Varicose Veins and Lymphedema	Circulatory 4	Hypertensive Chronic Kidney Disease
24	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
25	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
26	Circulatory 10	Varicose Veins and Lymphedema	Heart 11	Heart Failure
27	Circulatory 10	Varicose Veins and Lymphedema	Heart 12	Other Heart Diseases
28	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 3	Joint Pain
29	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
30	Circulatory 10	Varicose Veins and Lymphedema	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
31	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
32	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Gastrointestinal 2	Intestinal Obstruction and Ileus

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
33	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 4	Hypertensive Chronic Kidney Disease	Circulatory 9	Other Venous Embolism and Thrombosis
35	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
36	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
37	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
38	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
39	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
40	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
41	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
42	Endocrine 1	Hypothyroidism	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
43	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
44	Endocrine 1	Hypothyroidism	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
45	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
46	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
48	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
49	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
50	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
51	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
52	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
53	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
54	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
55	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
56	Gastrointestinal 4	Alcoholic Liver Disease, Chronic Hepatitis, Fibrosis and Cirrhosis of the Liver	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
57	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
58	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
59	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
60	Heart 11	Heart Failure	Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
61	Heart 11	Heart Failure	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
62	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
63	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
64	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
65	Heart 12	Other Heart Diseases	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
66	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
67	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
68	Heart 9	Valve Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
69	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
70	Infectious 1	C-diff, MRSA, E-coli	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
71	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
72	Musculoskeletal 3	Joint Pain	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
73	Musculoskeletal 3	Joint Pain	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
74	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
75	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
76	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
77	Neurological 10	Diabetes with neuropathy	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
78	Neurological 10	Diabetes with neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
79	Neurological 10	Diabetes with neuropathy	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
80	Neurological 12	Nondiabetic neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
81	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
82	Neurological 4	Alzheimer's disease and related dementias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
83	Neurological 5	Spinal Muscular Atrophy, Systemic Atrophy, and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
84	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
85	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
86	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
87	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
88	Renal 1	Chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
89	Renal 1	Chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
90	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
90	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
90	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
90	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
90	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
90	Respiratory 9	Respiratory Failure and Atelectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
90	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
90	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed from the CCW March 19, 2024.

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4. Proposed CY 2025 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 a policy 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 2025 case-mix weights, we used CY 2023 home health claims data with linked OASIS data (as of March 19, 2024). 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 2023 would be reflective of PDGM utilization and patient resource use for CY 2025. The proposed recalibrated case-mix weights will be updated based on more complete CY 2023 claims data in the final rule.

The claims data provide visit-level data and data on whether non-routine supplies (NRS) were 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 18 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 2022 home health cost reports. We use 2022 home health cost report data because it is the most complete cost report 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: After Step 2, each 30-day period is assigned to a clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. For each combination of those variables (which represent the 432 different payment groups that comprise the PDGM), we then calculate the 10th percentile of visits across all 30-day periods within a particular payment group. If a 30-day period's number of visits is less than the 10th percentile for their payment group, the 30-day period is classified as a Low Utilization Payment Adjustment (LUPA). If a payment group has a 10th percentile of visits that is less than two, we set the LUPA threshold for that payment group to be equal to two. That means if a 30-day period has one visit, it is classified as a LUPA and if it has two or more visits, it is not classified as a LUPA.

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 24 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 24: COEFFICIENT OF PAYMENT REGRESSION AND COEFFICIENT DIVIDED BY AVERAGE RESOURCE USE

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	$147.20	1.2%	0.0900
MMTA - Other - High Functional	$309.24	1.3%	0.1890
MMTA - Surgical Aftercare - Low Functional	-$43.89	1.2%	-0.0268
MMTA - Surgical Aftercare - Medium Functional	$148.94	1.2%	0.0910
MMTA - Surgical Aftercare - High Functional	$361.87	1.1%	0.2212
MMTA - Cardiac and Circulatory - Low Functional	-$13.84	6.1%	-0.0085
MMTA - Cardiac and Circulatory - Medium Functional	$128.54	5.9%	0.0786
MMTA - Cardiac and Circulatory - High Functional	$318.95	6.1%	0.1950
MMTA - Endocrine - Low Functional	$438.50	2.6%	0.2680
MMTA - Endocrine - Medium Functional	$559.02	2.3%	0.3417
MMTA - Endocrine - High Functional	$665.69	2.2%	0.4069
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$42.67	1.7%	-0.0261
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$152.74	1.6%	0.0934
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$299.33	1.7%	0.1830
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$20.70	1.6%	-0.0127
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$142.78	1.6%	0.0873
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$357.80	1.5%	0.2187
MMTA - Respiratory - Low Functional	-$0.70	2.8%	-0.0004
MMTA - Respiratory - Medium Functional	$160.36	2.2%	0.0980
MMTA - Respiratory - High Functional	$331.15	2.4%	0.2024
Behavioral Health - Low Functional	-$75.29	0.8%	-0.0460
Behavioral Health - Medium Functional	$118.73	0.8%	0.0726
Behavioral Health - High Functional	$282.70	0.7%	0.1728
Complex - Low Functional	-$77.00	0.9%	-0.0471
Complex - Medium Functional	$133.21	0.9%	0.0814
Complex - High Functional	$110.59	0.9%	0.0676
MS Rehab - Low Functional	$62.94	7.3%	0.0385
MS Rehab - Medium Functional	$192.17	7.2%	0.1175
MS Rehab - High Functional	$421.31	7.1%	0.2575
Neuro - Low Functional	$199.52	3.2%	0.1220
Neuro - Medium Functional	$384.96	3.1%	0.2353
Neuro - High Functional	$612.70	3.2%	0.3745
Wound - Low Functional	$599.73	5.3%	0.3666
Wound - Medium Functional	$759.02	4.1%	0.4639
Wound - High Functional	$946.38	4.8%	0.5785

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Admission Source with Timing (Community Early is excluded)			
Community - Late	-$571.81	63.5%	-0.3495
Institutional - Early	$343.60	19.1%	0.2100
Institutional - Late	$214.04	6.0%	0.1308
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$100.30		
Comorbidity Adjustment - Has at least one interaction from interaction list	$344.21		
Constant	$1,505.94		
Average Resource Use	$1,636.01		
Number of 30-day Periods	7,365,273		
Adjusted R-Squared	0.3156		

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW March 19, 2024.

The case-mix weights proposed for CY 2025 are listed in table 25 and will also be posted on the HHA Center web page [8] upon display of this proposed rule.

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

TABLE 25: CASE-MIX WEIGHTS AND LUPA THRESHOLDS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.0933	4
1FC21	Behavioral Health - High	Early - Community	1	1.1546	4
1FC31	Behavioral Health - High	Early - Community	2	1.3037	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.3033	3
2FC21	Behavioral Health - High	Early - Institutional	1	1.3646	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.5137	4
3FC11	Behavioral Health - High	Late - Community	0	0.7438	2
3FC21	Behavioral Health - High	Late - Community	1	0.8051	2
3FC31	Behavioral Health - High	Late - Community	2	0.9542	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.2241	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2854	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4345	4
1FA11	Behavioral Health - Low	Early - Community	0	0.8745	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9358	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0849	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0845	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1458	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2949	3
3FA11	Behavioral Health - Low	Late - Community	0	0.5250	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5863	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7354	2
4FA11	Behavioral Health - Low	Late - Institutional	0	1.0053	2
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0666	3
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2157	2
1FB11	Behavioral Health - Medium	Early - Community	0	0.9931	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0544	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2035	4
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2031	3
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2644	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4135	4
3FB11	Behavioral Health - Medium	Late - Community	0	0.6435	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.7049	2
3FB31	Behavioral Health - Medium	Late - Community	2	0.8539	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1239	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1852	3
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3343	3
1DC11	Complex - High	Early - Community	0	0.9881	2
1DC21	Complex - High	Early - Community	1	1.0494	2
1DC31	Complex - High	Early - Community	2	1.1985	2
2DC11	Complex - High	Early - Institutional	0	1.1981	3
2DC21	Complex - High	Early - Institutional	1	1.2594	3
2DC31	Complex - High	Early - Institutional	2	1.4085	3
3DC11	Complex - High	Late - Community	0	0.6386	2
3DC21	Complex - High	Late - Community	1	0.6999	2
3DC31	Complex - High	Late - Community	2	0.8490	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4DC11	Complex - High	Late - Institutional	0	1.1189	2
4DC21	Complex - High	Late - Institutional	1	1.1802	2
4DC31	Complex - High	Late - Institutional	2	1.3293	2
1DA11	Complex - Low	Early - Community	0	0.8734	2
1DA21	Complex - Low	Early - Community	1	0.9347	2
1DA31	Complex - Low	Early - Community	2	1.0838	2
2DA11	Complex - Low	Early - Institutional	0	1.0834	3
2DA21	Complex - Low	Early - Institutional	1	1.1448	3
2DA31	Complex - Low	Early - Institutional	2	1.2938	4
3DA11	Complex - Low	Late - Community	0	0.5239	2
3DA21	Complex - Low	Late - Community	1	0.5852	2
3DA31	Complex - Low	Late - Community	2	0.7343	2
4DA11	Complex - Low	Late - Institutional	0	1.0043	2
4DA21	Complex - Low	Late - Institutional	1	1.0656	2
4DA31	Complex - Low	Late - Institutional	2	1.2146	3
1DB11	Complex - Medium	Early - Community	0	1.0019	2
1DB21	Complex - Medium	Early - Community	1	1.0632	2
1DB31	Complex - Medium	Early - Community	2	1.2123	2
2DB11	Complex - Medium	Early - Institutional	0	1.2119	3
2DB21	Complex - Medium	Early - Institutional	1	1.2733	3
2DB31	Complex - Medium	Early - Institutional	2	1.4223	4
3DB11	Complex - Medium	Late - Community	0	0.6524	2
3DB21	Complex - Medium	Late - Community	1	0.7137	2
3DB31	Complex - Medium	Late - Community	2	0.8628	2
4DB11	Complex - Medium	Late - Institutional	0	1.1327	3
4DB21	Complex - Medium	Late - Institutional	1	1.1941	3
4DB31	Complex - Medium	Late - Institutional	2	1.3431	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1154	4
1HC21	MMTA - Cardiac - High	Early - Community	1	1.1768	4
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3258	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3255	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3868	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5359	4
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7659	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8272	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9763	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2463	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3076	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4567	4
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9120	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9733	4
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1224	3
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1221	3
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1834	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3325	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5625	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6238	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7729	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0429	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.1042	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2533	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	0.9991	4
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0604	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.2095	4
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2091	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.2704	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4195	4
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6495	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7109	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8599	2
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1299	4
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.1912	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3403	3
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3274	4
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3887	4
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5378	4
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5374	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.5987	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7478	4
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9779	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0392	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1883	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4582	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5195	4
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6686	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1885	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2498	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3989	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.3985	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4599	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.6089	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.8390	3
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.9003	3
3IA31	MMTA - Endocrine - Low	Late - Community	2	1.0494	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.3194	4
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3807	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.5297	4
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2622	5
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3235	4
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4726	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4722	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5335	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6826	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.9127	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9740	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.1231	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3930	4
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4543	4
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.6034	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1035	3
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1648	3
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3139	2
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3135	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.3748	3
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5239	3
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7539	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8153	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9643	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2343	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.2956	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4447	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8944	2
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9557	2
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1048	2
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.1044	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1657	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3148	3
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5449	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.6062	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7553	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0252	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0865	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2356	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0139	3
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0752	3
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2242	2
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2239	3
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.2852	4
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4343	4
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6643	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7257	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8747	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1447	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.2060	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3551	3
1KC11	MMTA - Infectious - High	Early - Community	0	1.1392	2
1KC21	MMTA - Infectious - High	Early - Community	1	1.2005	2
1KC31	MMTA - Infectious - High	Early - Community	2	1.3496	2
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3492	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4105	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5596	3
3KC11	MMTA - Infectious - High	Late - Community	0	0.7897	2
3KC21	MMTA - Infectious - High	Late - Community	1	0.8510	2
3KC31	MMTA - Infectious - High	Late - Community	2	1.0001	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2700	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3313	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4804	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9078	2
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9692	2
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1182	2
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1179	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1792	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3283	3
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5583	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6196	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7687	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0387	3
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.1000	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2491	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0078	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.0691	2
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2182	2
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2178	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.2791	3
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4282	3
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6583	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7196	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8686	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1386	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.1999	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3490	3
1AC11	MMTA - Other - High	Early - Community	0	1.1095	4
1AC21	MMTA - Other - High	Early - Community	1	1.1708	4
1AC31	MMTA - Other - High	Early - Community	2	1.3199	3
2AC11	MMTA - Other - High	Early - Institutional	0	1.3195	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.3808	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.5299	4
3AC11	MMTA - Other - High	Late - Community	0	0.7600	2
3AC21	MMTA - Other - High	Late - Community	1	0.8213	2
3AC31	MMTA - Other - High	Late - Community	2	0.9704	2
4AC11	MMTA - Other - High	Late - Institutional	0	1.2403	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.3017	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.4507	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9205	3
1AA21	MMTA - Other - Low	Early - Community	1	0.9818	3
1AA31	MMTA - Other - Low	Early - Community	2	1.1309	4
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1305	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.1918	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3409	3
3AA11	MMTA - Other - Low	Late - Community	0	0.5710	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6323	2
3AA31	MMTA - Other - Low	Late - Community	2	0.7814	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0513	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1126	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2617	3
1AB11	MMTA - Other - Medium	Early - Community	0	1.0105	4
1AB21	MMTA - Other - Medium	Early - Community	1	1.0718	4
1AB31	MMTA - Other - Medium	Early - Community	2	1.2209	3
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2205	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.2818	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4309	4
3AB11	MMTA - Other - Medium	Late - Community	0	0.6610	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7223	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8713	2
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1413	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2026	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3517	4
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1229	4
1LC21	MMTA - Respiratory - High	Early - Community	1	1.1842	3
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3333	3
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3329	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.3942	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5433	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7734	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8347	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9838	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2537	4
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3150	3
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4641	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9201	3
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9814	3
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1305	3
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1301	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1914	3
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3405	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5706	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6319	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7809	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0509	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.1122	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2613	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0185	4
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0798	3
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2289	3
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2285	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.2898	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4389	4
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6690	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7303	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8794	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1493	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2107	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3597	3
1GC11	MMTA - Surgical Aftercare – High	Early - Community	0	1.1417	3
1GC21	MMTA - Surgical Aftercare – High	Early - Community	1	1.2030	3
1GC31	MMTA - Surgical Aftercare – High	Early - Community	2	1.3521	3
2GC11	MMTA - Surgical Aftercare – High	Early - Institutional	0	1.3517	4
2GC21	MMTA - Surgical Aftercare – High	Early - Institutional	1	1.4130	4
2GC31	MMTA - Surgical Aftercare – High	Early - Institutional	2	1.5621	4
3GC11	MMTA - Surgical Aftercare – High	Late - Community	0	0.7922	2
3GC21	MMTA - Surgical Aftercare – High	Late - Community	1	0.8535	2
3GC31	MMTA - Surgical Aftercare – High	Late - Community	2	1.0026	2
4GC11	MMTA - Surgical Aftercare – High	Late - Institutional	0	1.2725	3
4GC21	MMTA - Surgical Aftercare – High	Late - Institutional	1	1.3338	4
4GC31	MMTA - Surgical Aftercare – High	Late - Institutional	2	1.4829	4
1GA11	MMTA - Surgical Aftercare – Low	Early - Community	0	0.8937	2
1GA21	MMTA - Surgical Aftercare – Low	Early - Community	1	0.9550	2
1GA31	MMTA - Surgical Aftercare – Low	Early - Community	2	1.1041	2
2GA11	MMTA - Surgical Aftercare – Low	Early - Institutional	0	1.1037	3
2GA21	MMTA - Surgical Aftercare – Low	Early - Institutional	1	1.1650	3
2GA31	MMTA - Surgical Aftercare – Low	Early - Institutional	2	1.3141	3
3GA11	MMTA - Surgical Aftercare – Low	Late - Community	0	0.5442	2
3GA21	MMTA - Surgical Aftercare – Low	Late - Community	1	0.6055	2
3GA31	MMTA - Surgical Aftercare – Low	Late - Community	2	0.7545	2
4GA11	MMTA - Surgical Aftercare – Low	Late - Institutional	0	1.0245	2
4GA21	MMTA - Surgical Aftercare – Low	Late - Institutional	1	1.0858	3
4GA31	MMTA - Surgical Aftercare – Low	Late - Institutional	2	1.2349	3
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0115	3
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.0728	3
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2219	3
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2216	3
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2829	4
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4319	4
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6620	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7233	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8724	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1424	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2037	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3528	4
1EC11	MS Rehab - High	Early - Community	0	1.1780	4
1EC21	MS Rehab - High	Early - Community	1	1.2393	4
1EC31	MS Rehab - High	Early - Community	2	1.3884	4
2EC11	MS Rehab - High	Early - Institutional	0	1.3880	5
2EC21	MS Rehab - High	Early - Institutional	1	1.4493	5
2EC31	MS Rehab - High	Early - Institutional	2	1.5984	5
3EC11	MS Rehab - High	Late - Community	0	0.8285	2
3EC21	MS Rehab - High	Late - Community	1	0.8898	2
3EC31	MS Rehab - High	Late - Community	2	1.0389	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4EC11	MS Rehab - High	Late - Institutional	0	1.3088	4
4EC21	MS Rehab - High	Late - Institutional	1	1.3702	4
4EC31	MS Rehab - High	Late - Institutional	2	1.5192	4
1EA11	MS Rehab - Low	Early - Community	0	0.9590	4
1EA21	MS Rehab - Low	Early - Community	1	1.0203	4
1EA31	MS Rehab - Low	Early - Community	2	1.1694	4
2EA11	MS Rehab - Low	Early - Institutional	0	1.1690	5
2EA21	MS Rehab - Low	Early - Institutional	1	1.2303	5
2EA31	MS Rehab - Low	Early - Institutional	2	1.3794	5
3EA11	MS Rehab - Low	Late - Community	0	0.6095	2
3EA21	MS Rehab - Low	Late - Community	1	0.6708	2
3EA31	MS Rehab - Low	Late - Community	2	0.8198	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.0898	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.1511	4
4EA31	MS Rehab - Low	Late - Institutional	2	1.3002	4
1EB11	MS Rehab - Medium	Early - Community	0	1.0380	5
1EB21	MS Rehab - Medium	Early - Community	1	1.0993	5
1EB31	MS Rehab - Medium	Early - Community	2	1.2483	4
2EB11	MS Rehab - Medium	Early - Institutional	0	1.2480	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.3093	5
2EB31	MS Rehab - Medium	Early - Institutional	2	1.4584	5
3EB11	MS Rehab - Medium	Late - Community	0	0.6884	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7498	2
3EB31	MS Rehab - Medium	Late - Community	2	0.8988	2
4EB11	MS Rehab - Medium	Late - Institutional	0	1.1688	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2301	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.3792	4
1BC11	Neuro - High	Early - Community	0	1.2950	4
1BC21	Neuro - High	Early - Community	1	1.3563	4
1BC31	Neuro - High	Early - Community	2	1.5054	4
2BC11	Neuro - High	Early - Institutional	0	1.5050	5
2BC21	Neuro - High	Early - Institutional	1	1.5663	5
2BC31	Neuro - High	Early - Institutional	2	1.7154	4
3BC11	Neuro - High	Late - Community	0	0.9455	2
3BC21	Neuro - High	Late - Community	1	1.0068	3
3BC31	Neuro - High	Late - Community	2	1.1559	3
4BC11	Neuro - High	Late - Institutional	0	1.4258	4
4BC21	Neuro - High	Late - Institutional	1	1.4871	4
4BC31	Neuro - High	Late - Institutional	2	1.6362	4
1BA11	Neuro - Low	Early - Community	0	1.0424	4
1BA21	Neuro - Low	Early - Community	1	1.1038	4
1BA31	Neuro - Low	Early - Community	2	1.2528	3
2BA11	Neuro - Low	Early - Institutional	0	1.2525	4
2BA21	Neuro - Low	Early - Institutional	1	1.3138	4
2BA31	Neuro - Low	Early - Institutional	2	1.4629	4
3BA11	Neuro - Low	Late - Community	0	0.6929	2
3BA21	Neuro - Low	Late - Community	1	0.7542	2
3BA31	Neuro - Low	Late - Community	2	0.9033	2

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4BA11	Neuro - Low	Late - Institutional	0	1.1733	3
4BA21	Neuro - Low	Late - Institutional	1	1.2346	3
4BA31	Neuro - Low	Late - Institutional	2	1.3837	3
1BB11	Neuro - Medium	Early - Community	0	1.1558	4
1BB21	Neuro - Medium	Early - Community	1	1.2171	4
1BB31	Neuro - Medium	Early - Community	2	1.3662	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3658	5
2BB21	Neuro - Medium	Early - Institutional	1	1.4271	5
2BB31	Neuro - Medium	Early - Institutional	2	1.5762	5
3BB11	Neuro - Medium	Late - Community	0	0.8063	2
3BB21	Neuro - Medium	Late - Community	1	0.8676	2
3BB31	Neuro - Medium	Late - Community	2	1.0167	2
4BB11	Neuro - Medium	Late - Institutional	0	1.2866	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3479	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4970	4
1CC11	Wound - High	Early - Community	0	1.4990	4
1CC21	Wound - High	Early - Community	1	1.5603	4
1CC31	Wound - High	Early - Community	2	1.7094	4
2CC11	Wound - High	Early - Institutional	0	1.7090	5
2CC21	Wound - High	Early - Institutional	1	1.7703	4
2CC31	Wound - High	Early - Institutional	2	1.9194	4
3CC11	Wound - High	Late - Community	0	1.1494	3
3CC21	Wound - High	Late - Community	1	1.2108	3
3CC31	Wound - High	Late - Community	2	1.3598	3
4CC11	Wound - High	Late - Institutional	0	1.6298	4
4CC21	Wound - High	Late - Institutional	1	1.6911	4
4CC31	Wound - High	Late - Institutional	2	1.8402	4
1CA11	Wound - Low	Early - Community	0	1.2871	4
1CA21	Wound - Low	Early - Community	1	1.3484	4
1CA31	Wound - Low	Early - Community	2	1.4975	4
2CA11	Wound - Low	Early - Institutional	0	1.4971	4
2CA21	Wound - Low	Early - Institutional	1	1.5584	4
2CA31	Wound - Low	Early - Institutional	2	1.7075	4
3CA11	Wound - Low	Late - Community	0	0.9376	2
3CA21	Wound - Low	Late - Community	1	0.9989	3
3CA31	Wound - Low	Late - Community	2	1.1480	3
4CA11	Wound - Low	Late - Institutional	0	1.4179	3
4CA21	Wound - Low	Late - Institutional	1	1.4792	4
4CA31	Wound - Low	Late - Institutional	2	1.6283	4
1CB11	Wound - Medium	Early - Community	0	1.3844	4
1CB21	Wound - Medium	Early - Community	1	1.4457	4
1CB31	Wound - Medium	Early - Community	2	1.5948	4
2CB11	Wound - Medium	Early - Institutional	0	1.5945	4
2CB21	Wound - Medium	Early - Institutional	1	1.6558	5
2CB31	Wound - Medium	Early - Institutional	2	1.8049	4
3CB11	Wound - Medium	Late - Community	0	1.0349	3
3CB21	Wound - Medium	Late - Community	1	1.0962	3
3CB31	Wound - Medium	Late - Community	2	1.2453	3

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2025	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
4CB11	Wound - Medium	Late - Institutional	0	1.5153	4
4CB21	Wound - Medium	Late - Institutional	1	1.5766	4
4CB31	Wound - Medium	Late - Institutional	2	1.7257	4

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW March 19, 2024.

Changes to the PDGM case-mix weights are implemented in a budget neutral manner by multiplying the CY 2025 national standardized 30-day

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period payment rate by a case-mix budget neutrality factor. Typically, the case-mix weight budget neutrality factor is also calculated using the most recent, complete home health claims data available. For CY 2025, we will continue the practice of using the most recent complete home health claims data at the time of rulemaking, which is CY 2023 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 2025 PDGM case-mix weights (developed using CY 2023 home health claims data) are applied to CY 2023 utilization (claims) data are equal to total payments when CY 2024 PDGM case-mix weights (developed using CY 2022 home health claims data) are applied to CY 2023 utilization data. This produces a case-mix budget neutrality factor for CY 2025 of 1.0035.

We invite public comments on the CY 2025 proposed case-mix weights and proposed case-mix weight budget neutrality factor.

5. Suggested Reassignment of Specific ICD–10–CM Codes Under the PDGM

a. Background

The 2009 final rule, ''HIPAA Administrative Simplification: Modifications to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS'' (74 FR 3328, January 16, 2009), set October 1, 2013, as the compliance date for all covered entities under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) medical data code sets. The ICD–10–CM diagnosis codes are granular and specific and provide HHAs a better opportunity to report codes that best reflect the patient's conditions that support the need for home health services. However, as stated in the CY 2019 HH PPS final rule with comment period (83 FR 56473), because the ICD–10–CM is comprehensive, it also contains many codes that may not support the need for home health services. For example, diagnosis codes that indicate death as the outcome are Medicare covered codes but are not relevant to home health. In addition, diagnosis and procedure coding guidelines may specify the sequence of ICD–10–CM coding conventions. For example, the underlying condition must be listed first (for example, Parkinson's disease must be listed prior to Dementia if both codes were listed on a claim). Therefore, not all the ICD–10–CM diagnosis codes are appropriate as principal diagnosis codes for grouping home health periods into clinical groups or to be placed into a comorbidity subgroup when listed as a secondary diagnosis. As such, each ICD–10–CM diagnosis code is assigned, including those diagnosis codes designated as ''not assigned'' (NA), to a clinical group and comorbidity subgroup within the HH PPS grouper software (HHGS). We reminded readers the ICD–10–CM diagnosis code list is updated each fiscal year with an effective date of October 1st and therefore, the HH PPS is generally subject to a minimum of two HHGS releases, one in October and one in January of each year, to ensure that claims are submitted with the most current code set available. Likewise, there may be new ICD–10–CM diagnosis codes created (for example, codes for emergency use) or a new or revised edit in the Medicare Code Editor (MCE) so an update to the HHGS may occur on the first of each quarter (January, April, July, October). We encourage readers to check the HHGS routinely at these times, as we do not anticipate posting changes to the home health web page.

b. Methodology for ICD–10–CM Diagnosis Code Assignments

Although it is not our intent to review all ICD–10–CM diagnosis codes each year, we recognize that occasionally some ICD–10–CM diagnosis codes may require changes to their assigned clinical group and/or comorbidity subgroup. For example, there may be an update to the MCE unacceptable principal diagnosis list, or we receive public comments from interested parties requesting specific changes. Any addition or removal of a specific diagnosis code to the ICD–10–CM code set (for example, three new diagnosis codes, Z28.310, Z28.311 and Z28.39, for reporting COVID–19 vaccination status were effective April 1, 2022) or minor tweaks to a descriptor of an existing ICD–10–CM diagnosis code generally could be implemented as appropriate and may not be discussed in rulemaking.

We rely on the expert opinion of our clinical reviewers (for example, nurse consultants and medical officers) and current ICD–10–CM coding guidelines to determine if the ICD–10–CM diagnosis codes under review for reassignment are significantly similar or different to the existing clinical group and/or comorbidity subgroup assignment. As we stated in the CY 2018 HH PPS proposed rule (82 FR 35313), the intent of the clinical groups is to reflect the reported principal diagnosis, clinical relevance, and coding guidelines and conventions. Therefore, for the purposes of assignment of ICD–10–CM diagnosis codes into the PDGM clinical groups we would not conduct additional statistical analysis as such decisions are clinically based and the clinical groups are part of the overall case-mix weights.

As we noted in the CY 2019 HH PPS final rule with comment period (83 FR 56486), the home health-specific comorbidity list is based on the principles of patient assessment by body systems and their associated diseases, conditions, and injuries to develop larger categories of conditions that identified clinically relevant relationships associated with increased 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. If specific ICD–10–CM diagnosis codes are to be reassigned to a different comorbidity subgroup (including NA), we will first evaluate the clinical characteristics (as discussed previously for clinical groups) and if the ICD–10–CM diagnosis code does not meet the clinical criteria, then no reassignment will occur. However, if an ICD–10–CM diagnosis code does meet the clinical criteria for a comorbidity subgroup reassignment, then we will evaluate the resource consumption associated with the ICD–10–CM diagnosis codes, the current assigned comorbidity subgroup, and the proposed (reassigned) comorbidity subgroup. This analysis is to ensure that any reassignment of an ICD–10–CM diagnosis code (if reported as secondary) in any given year would not significantly alter the overall resource use of a specific comorbidity subgroup. For resource consumption, we use non-LUPA 30-day periods to evaluate the total number of 30-day periods for the comorbidity subgroup(s) and the ICD–10–CM diagnosis code, the average number of visits per 30-day periods for the comorbidity subgroup(s) and the ICD–10–CM diagnosis code, and the average resource use for the comorbidity subgroup(s) and the ICD–10–CM diagnosis code. The average resource use measures the costs associated with visits performed during a home health period and was previously described in the CY 2019 HH PPS final rule with comment period (83 FR 56450).

c. Request for ICD–10–CM Diagnosis Code Reassignments to a PDGM Clinical Group or Comorbidity Subgroup—Renal 3 Comorbidity Subgroup

We received questions from interested parties regarding the ICD–10–CM diagnosis codes N30.00– (acute cystitis) and the ICD–10–CM diagnosis code N39.0 (urinary tract infection, site not specified). Specifically, CMS received a request to reassign N30.00 to the same clinical and comorbidity group as N39.0. The ICD–10–CM diagnosis codes N30.00– (acute cystitis) are currently assigned to clinical group J (MMTA—Gastrointestinal tract and Genitourinary system) when listed as a primary diagnosis and not assigned to a comorbidity subgroup when listed as a secondary diagnosis. The ICD–10–CM diagnosis code N39.0 (urinary tract infection, site not specified) is currently assigned to clinical group J (MMTA—Gastrointestinal tract and Genitourinary system) when listed as a primary diagnosis and assigned to the renal 3 comorbidity subgroup when listed as a secondary diagnosis.

We reviewed the ICD–10–CM diagnosis codes related to cystitis (N30.–) and determined all 14 of the codes are not assigned to a comorbidity subgroup when listed as a secondary diagnosis. Our clinical reviewers advised that cystitis, including N30.00– (acute cystitis), is to report inflammation of the urinary bladder; whereas N39.0 (urinary tract infection, site not specified) is to report the presence of the infectious microorganisms in the urinary tract system. In addition, we evaluated resource consumption related to the comorbidity subgroup renal 3, as well as diagnosis codes N30.00– (acute cystitis) and N39.0 (urinary tract infection, site not specified) and found that acute cystitis on average has a lower resource use than urinary tract infection. As described earlier, based on clinical review and resources use analysis, the ICD–10–CM diagnosis codes N30.00– (acute cystitis) are currently assigned to the most appropriate comorbidity group, not assigned. Therefore, we are not proposing a reassignment of N30.00– (acute cystitis) at this time.

E. Proposed CY 2025 Home Health Payment Rate Updates

1. Proposed CY 2025 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 2024 HH PPS final rule (88 FR 77726), we finalized a rebasing of the home health market basket to reflect 2021 cost report data. We also finalized a policy for CY 2024 and subsequent years that the labor-related share would be 74.9 percent and the non-labor-related share would be 25.1 percent. A detailed description of how we rebased the HHA market basket and labor-related share is available in the CY 2024 HH PPS final rule (88 FR 77726 through 77742).

In the CY 2015 HH PPS final rule (79 FR 38384), we finalized our methodology for calculating and applying the multifactor productivity adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) 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)), the market basket percentage under the HH PPS 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 change in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as ''private nonfarm business total factor productivity''. We refer readers to *https://www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.*

The proposed home health update percentage for CY 2025 is based on the estimated home health market basket percentage increase, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.0 percent (based on IHS Global Inc.'s first quarter 2024 forecast with historical data through fourth-quarter 2023). The estimated CY 2025 home health market basket percentage increase of 3.0 percent is then reduced by a productivity adjustment, in accordance with section 1895(b)(3)(B)(vi) of the Act. Based on IGI's first quarter 2024 forecast, the proposed productivity adjustment is currently estimated to be 0.5 percentage point for CY 2025. Therefore, the proposed productivity-adjusted CY 2025 home health market basket update is 2.5 percent (3.0 percent market basket percentage increase, reduced by a 0.5 percentage point productivity adjustment). Furthermore, we propose that if more recent data subsequently become available (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase and productivity adjustment in the final rule.

Section 1895(b)(3)(B)(v) of the Act requires that the home health percentage 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 2025, the proposed home health payment update percentage is 0.5 percent (2.5 percent minus 2 percentage points).

We invite public comment on our proposals for the CY 2025 home health market basket percentage increase and productivity adjustment.

2. Proposed Adoption of the CBSA Delineations for Wage Index

In general, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses.

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 2025 HH PPS wage index value for CBSA 46300, Twin Falls, Idaho, will be 0.8555. Bulletin No. 17–01 is available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_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 Area 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 home health wage index for CY 2022. Specifically, the updates consisted of changes to NECTA delineations and the re-designation of a single rural county into a newly created Micropolitan Statistical Area. The Medicare home health 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. In other words, these OMB updates did not affect any geographic areas for purposes of the HH PPS wage index calculation.

In the CY 2021 HH PPS final rule (85 FR 70298), we finalized our proposal to adopt the revised OMB delineations with a 5-percent cap on wage index decreases in CY 2021. As described in the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we finalized a policy that the CY HH PPS wage index would include a 5-percent cap on wage index decreases for CY 2023 and each subsequent year. Specifically, we finalized for CY 2023 and subsequent years, the application of a permanent 5-percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we finalized a policy requiring that a geographic area's wage index for CY 2023 would not be less than 95 percent of its final wage index for CY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area's wage index would not be less than 95 percent of its wage index calculated in the prior CY. Previously this methodology was applied to all the counties that make up a CBSA or statewide rural area. However, as discussed in section II.E.2. of this proposed rule, if we adopt the proposed revised OMB delineations, we are also proposing that this methodology would also be applied to individual counties.

On July 21, 2023, OMB issued Bulletin No. 23–01, which updates and supersedes OMB Bulletin No. 20–01, issued on March 6, 2020. OMB Bulletin No. 23–01 establishes revised delineations for the MSAs, Micropolitan Statistical Areas, Combined Statistical Areas, and Metropolitan Divisions, collectively referred to as Core Based Statistical Areas (CBSAs). According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (CBSAs) (the ''2020 Standards''), which appeared in the **Federal Register** (86 FR 37770 through 37778) on July 16, 2021, and application of those standards to Census Bureau population and journey-to-work data (for example, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). A copy of OMB Bulletin No. 23–01 is available online at: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

The July 21, 2023, OMB Bulletin No. 23–01 contains a number of significant changes. For example, there are new CBSAs, urban counties that have become rural, rural counties that have become urban, and existing CBSAs that have been split apart. We believe it is important for the HH PPS wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We further believe that using the most current OMB delineations would increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We are proposing to implement the new OMB delineations as described in the July 21, 2023, OMB Bulletin No. 23–01 for the HH PPS wage index effective beginning in CY 2025. This proposal is also consistent with the proposals to adopt the revised OMB delineations in the IPPS and other post-acute care payment systems.

a. Micropolitan Statistical Areas

As discussed in the CY 2006 HH PPS proposed rule (70 FR 40788) and final rule (70 FR 68132), CMS considered how to use the Micropolitan statistical area definitions in the calculation of the wage index. At the time, OMB defined a ''Micropolitan Statistical Area'' as a ''CBSA'' associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We referred to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action would be to treat Micropolitan Areas as ''rural'' and include them in the calculation of each state's home health rural wage index (see 70 FR 40788 and 70 FR 68132). Thus, the HH PPS statewide rural wage index is determined using IPPS hospital data from hospitals located in non-Metropolitan Statistical Areas (MSAs). In the CY 2021 HH PPS final rule (85 FR 70298), we finalized a policy to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

The OMB ''2020 Standards'' continue to define a ''Micropolitan Statistical Area'' as a CBSA with at least one urban area that has a population of at least

10,000, but less than 50,000. The Micropolitan Statistical Area comprises the central county or counties containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county, or counties as measured through commuting (86 FR 37778). Overall, there are the same number of Micropolitan Areas (542) under the new OMB delineations based on the 2020 Census as there were using the 2010 Census. We note, however, that a number of urban counties have switched status and have joined or become Micropolitan Areas, and some counties that once were part of a Micropolitan Area, and thus were treated as rural, have become urban based on the 2020 Decennial Census data. We believe that the best course of action would be to continue our established policy and include Micropolitan Areas in each state's rural wage index as these areas continue to be defined as having relatively small urban cores (populations of 10,000 to 49,999). Therefore, in conjunction with our proposal to implement the new OMB labor market delineations beginning in CY 2025, and consistent with the treatment of Micropolitan Areas under the IPPS, we are also proposing to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

b. Change to County-Equivalents in the State of Connecticut

In a June 6, 2022, Notice (87 FR 34235–34240), the Census Bureau announced that it was implementing the State of Connecticut's request to replace the eight counties in the State with nine new ''Planning Regions.'' Planning regions are included in OMB Bulletin No. 23–01 and now serve as county-equivalents within the CBSA system. We have evaluated the change and are proposing to adopt the planning regions as county equivalents for wage index purposes. We believe it is necessary to adopt this migration from counties to planning region county-equivalents in order to maintain consistency with our established policy of adopting the most recent OMB updates. We are providing the following crosswalk in table 26 for counties located in Connecticut with the current and proposed Federal Information Processing Series (FIPS) county and county-equivalent codes and CBSA assignments.

TABLE 26: CROSSWALK OF CONNECTICUT COUNTY EQUIVALENTS

FIPS County Code	County	Old CBSA or Non-urban Area	New FIPS County Code	FY 2025 Planning Region	New CBSA or Non-urban Area
09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
09001	FAIRFIELD	14860	09120	GREATER BRIDGEPORT	14860
09003	HARTFORD	25540	09110	CAPITOL	25540
09005	LITCHFIELD	99907	09160	NORTHWEST HILLS	99907
09007	MIDDLESEX	25540	09130	LOWER CONNECTICUT RIVER VALLEY	25540
09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
09011	NEW LONDON	35980	09180	SOUTHEASTERN CONNECTICUT	35980
09013	TOLLAND	25540	09110	CAPITOL	25540
09015	WINDHAM	49340	09150	NORTHEASTERN CONNECTICUT	99907

c. Urban Counties That Would Become Rural

Under the revised OMB statistical area delineations (based upon OMB Bulletin No. 23–01), a total of 53 counties (and county equivalents) that are currently considered urban would be considered rural beginning in CY 2025. Table 27 lists the 53 counties that would become rural if we adopt as final our proposal to implement the revised OMB delineations.

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TABLE 27: URBAN COUNTIES THAT WOULD CHANGE TO RURAL STATUS

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name
01129	WASHINGTON	AL	33660	Mobile, AL
05025	CLEVELAND	AR	38220	Pine Bluff, AR
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
05069	JEFFERSON	AR	38220	Pine Bluff, AR
05079	LINCOLN	AR	38220	Pine Bluff, AR
10005	SUSSEX	DE	41540	Salisbury, MD-DE
13171	LAMAR	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17077	JACKSON	IL	16060	Carbondale-Marion, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
17183	VERMILION	IL	19180	Danville, IL
17199	WILLIAMSON	IL	16060	Carbondale-Marion, IL
18121	PARKE	IN	45460	Terre Haute, IN
18133	PUTNAM	IN	26900	Indianapolis-Carmel-Anderson, IN
18161	UNION	IN	17140	Cincinnati, OH-KY-IN
21091	HANCOCK	KY	36980	Owensboro, KY
21101	HENDERSON	KY	21780	Evansville, IN-KY
22045	IBERIA	LA	29180	Lafayette, LA
24001	ALLEGANY	MD	19060	Cumberland, MD-WV
24047	WORCESTER	MD	41540	Salisbury, MD-DE
25011	FRANKLIN	MA	44140	Springfield, MA
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
31051	DIXON	NE	43580	Sioux City, IA-NE-SD
36123	YATES	NY	40380	Rochester, NY
37049	CRAVEN	NC	35100	New Bern, NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
37087	HAYWOOD	NC	11700	Asheville, NC
37103	JONES	NC	35100	New Bern, NC
37137	PAMLICO	NC	35100	New Bern, NC
42037	COLUMBIA	PA	14100	Bloomsburg-Berwick, PA
42085	MERCER	PA	49660	Youngstown-Warren-Boardman, OH-PA
42089	MONROE	PA	20700	East Stroudsburg, PA
42093	MONTOUR	PA	14100	Bloomsburg-Berwick, PA
42103	PIKE	PA	35084	Newark, NJ-PA
45027	CLARENDON	SC	44940	Sumter, SC
48431	STERLING	TX	41660	San Angelo, TX
49003	BOX ELDER	UT	36260	Ogden-Clearfield, UT
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54043	LINCOLN	WV	16620	Charleston, WV
54057	MINERAL	WV	19060	Cumberland, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name
72055	GUANICA	PR	49500	Yauco, PR
72081	LARES	PR	10380	Aguadilla-Isabela, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR
72141	UTUADO	PR	10380	Aguadilla-Isabela, PR

d. Rural Counties That Would Become Urban

Under the revised OMB statistical area delineations (based upon OMB Bulletin No. 23–01), a total of 54 counties (and county equivalents) that are currently located in rural areas would be considered located in urban areas under the revised OMB delineations beginning in CY 2025. Table 28 lists the 54 counties that would be urban if we adopt as final our proposal to implement the revised OMB delineations.

TABLE 28: RURAL COUNTIES THAT WOULD CHANGE TO URBAN STATUS

FIPS County Code	County Name	State	Proposed CY 2025 CBSA	Proposed CY 2025 CBSA Name
01087	MACON	AL	12220	Auburn-Opelika, AL
01127	WALKER	AL	13820	Birmingham, AL
12133	WASHINGTON	FL	37460	Panama City-Panama City Beach, FL
13187	LUMPKIN	GA	12054	Atlanta-Sandy Springs-Roswell, GA
15005	KALAWAO	HI	27980	Kahului-Wailuku, HI
17053	FORD	IL	16580	Champaign-Urbana, IL
17127	MASSAC	IL	37140	Paducah, KY-IL
18159	TIPTON	IN	26900	Indianapolis-Carmel-Greenwood, IN
18179	WELLS	IN	23060	Fort Wayne, IN
20021	CHEROKEE	KS	27900	Joplin, MO-KS
21007	BALLARD	KY	37140	Paducah, KY-IL
21039	CARLISLE	KY	37140	Paducah, KY-IL
21127	LAWRENCE	KY	26580	Huntington-Ashland, WV-KY-OH
21139	LIVINGSTON	KY	37140	Paducah, KY-IL
21145	MC CRACKEN	KY	37140	Paducah, KY-IL
21179	NELSON	KY	31140	Louisville/Jefferson County, KY-IN
22053	JEFFRSON DAVIS	LA	29340	Lake Charles, LA
22083	RICHLAND	LA	33740	Monroe, LA
26015	BARRY	MI	24340	Grand Rapids-Wyoming-Kentwood, MI
26019	BENZIE	MI	45900	Traverse City, MI
26055	GRAND TRAVERSE	MI	45900	Traverse City, MI
26079	KALKASKA	MI	45900	Traverse City, MI
26089	LEELANAU	MI	45900	Traverse City, MI
27133	ROCK	MN	43620	Sioux Falls, SD-MN
28009	BENTON	MS	32820	Memphis, TN-MS-AR
28123	SCOTT	MS	27140	Jackson, MS
30007	BROADWATER	MT	25740	Helena, MT
30031	GALLATIN	MT	14580	Bozeman, MT
30043	JEFFERSON	MT	25740	Helena, MT
30049	LEWIS AND CLARK	MT	25740	Helena, MT
30061	MINERAL	MT	33540	Missoula, MT
32019	LYON	NV	39900	Reno, NV
37125	MOORE	NC	38240	Pinehurst-Southern Pines, NC
38049	MCHENRY	ND	33500	Minot, ND
38075	RENVILLE	ND	33500	Minot, ND
38101	WARD	ND	33500	Minot, ND
39007	ASHTABULA	OH	17410	Cleveland, OH
39043	ERIE	OH	41780	Sandusky, OH
41013	CROOK	OR	13460	Bend, OR
41031	JEFFERSON	OR	13460	Bend, OR
42073	LAWRENCE	PA	38300	Pittsburgh, PA
45087	UNION	SC	43900	Spartanburg, SC
46033	CUSTER	SD	39660	Rapid City, SD
47081	HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	ARANSAS	TX	18580	Corpus Christi, TX
48035	BOSQUE	TX	47380	Waco, TX
48079	COCHRAN	TX	31180	Lubbock, TX
48169	GARZA	TX	31180	Lubbock, TX
48219	HOCKLEY	TX	31180	Lubbock, TX
48323	MAVERICK	TX	20580	Eagle Pass, TX
48407	SAN JACINTO	TX	26420	Houston-Pasadena-The Woodlands, TX
51063	FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
51181	SURRY	VA	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
55123	VERNON	WI	29100	La Crosse-Onalaska, WI-MN

e. Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, several urban counties would shift from one urban CBSA to a new or existing urban CBSA under our proposal to adopt the revised OMB delineations. In other cases, applying the new OMB delineations would involve a change only in CBSA name or number, while the CBSA would continue to encompass the same constituent counties. For example, CBSA 35154 (New Brunswick-Lakewood, NJ) would experience both a change to its number and its name and become CBSA 29484 (Lakewood-New Brunswick, NJ), while all three of its constituent counties would remain the same. In other cases, only the name of the CBSA would be modified. Table 29 lists CBSAs that would change in name and/or CBSA number only, but the

constituent counties would not change (except in instances where an urban county became rural or a rural county became urban, as discussed in the previous section).

TABLE 29: URBAN AREAS WITH CBSA NAME AND/OR NUMBER CHANGE

Current CBSA Code	Current CBSA Name	Proposed CY 2025 CBSA Code	Proposed CY 2025 CBSA Name
10380	Aguadilla-Isabela, PR	10380	Aguadilla, PR
10540	Albany-Lebanon, OR	10540	Albany, OR
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock-San Marcos, TX
12540	Bakersfield, CA	12540	Bakersfield-Delano, CA
13820	Birmingham-Hoover, AL	13820	Birmingham, AL
13980	Blacksburg-Christiansburg, VA	13980	Blacksburg-Christiansburg-Radford, VA
15260	Brunswick, GA	15260	Brunswick-St. Simons, GA
15680	California-Lexington Park, MD	30500	Lexington Park, MD
16540	Chambersburg-Waynesboro, PA	16540	Chambersburg, PA
16984	Chicago-Naperville-Evanston, IL	16984	Chicago-Naperville-Schaumburg, IL
17460	Cleveland-Elyria, OH	17410	Cleveland, OH
19430	Dayton-Kettering, OH	19430	Dayton-Kettering-Beavercreek, OH
19740	Denver-Aurora-Lakewood, CO	19740	Denver-Aurora-Centennial, CO
21060	Elizabethtown-Fort Knox, KY	21060	Elizabethtown, KY
21780	Evansville, IN-KY	21780	Evansville, IN
21820	Fairbanks, AK	21820	Fairbanks-College, AK
22660	Fort Collins, CO	22660	Fort Collins-Loveland, CO
23224	Frederick-Gaithersburg-Rockville, MD	23224	Frederick-Gaithersburg-Bethesda, MD
23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
24340	Grand Rapids-Kentwood, MI	24340	Grand Rapids-Wyoming-Kentwood, MI
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Greer, SC
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Port Royal, SC
26380	Houma-Thibodaux, LA	26380	Houma-Bayou Cane-Thibodaux, LA
26420	Houston-The Woodlands-Sugar Land, TX	26420	Houston-Pasadena-The Woodlands, TX
26900	Indianapolis-Carmel-Anderson, IN	26900	Indianapolis-Carmel-Greenwood, IN
27900	Joplin, MO	27900	Joplin, MO-KS
27980	Kahului-Wailuku-Lahaina, HI	27980	Kahului-Wailuku, HI
29404	Lake County-Kenosha County, IL-WI	29404	Lake County, IL
29820	Las Vegas-Henderson-Paradise, NV	29820	Las Vegas-Henderson-North Las Vegas, NV
31020	Longview, WA	31020	Longview-Kelso, WA
34740	Muskegon, MI	34740	Muskegon-Norton Shores, MI
34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	34820	Myrtle Beach-Conway-North Myrtle Beach, SC
35084	Newark, NJ-PA	35084	Newark, NJ
35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
35840	North Port-Sarasota-Bradenton, FL	35840	North Port-Bradenton-Sarasota, FL
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Fremont-Berkeley, CA
36260	Ogden-Clearfield, UT	36260	Ogden, UT
36540	Omaha-Council Bluffs, NE-IA	36540	Omaha, NE-IA
37460	Panama City, FL	37460	Panama City-Panama City Beach, FL
39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
39340	Provo-Orem, UT	39340	Provo-Orem-Lehi, UT
39540	Racine, WI	39540	Racine-Mount Pleasant, WI
41540	Salisbury, MD-DE	41540	Salisbury, MD
41620	Salt Lake City, UT	41620	Salt Lake City-Murray, UT
42680	Sebastian-Vero Beach, FL	42680	Sebastian-Vero Beach-West Vero Corridor, FL
42700	Sebring-Avon Park, FL	42700	Sebring, FL
43620	Sioux Falls, SD	43620	Sioux Falls, SD-MN
44420	Staunton, VA	44420	Staunton-Stuarts Draft, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
45540	The Villages, FL	48680	Wildwood-The Villages, FL

Current CBSA Code	Current CBSA Name	Proposed CY 2025 CBSA Code	Proposed CY 2025 CBSA Name
47220	Vineland-Bridgeton, NJ	47220	Vineland, NJ
47260	Virginia Beach-Norfolk-Newport News, VA-NC	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
48140	Wausau-Weston, WI	48140	Wausau, WI
48300	Wenatchee, WA	48300	Wenatchee-East Wenatchee, WA
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL
49340	Worcester, MA-CT	49340	Worcester, MA
49660	Youngstown-Warren-Boardman, OH-PA	49660	Youngstown-Warren, OH

In some cases, all urban counties from a CY 2024 CBSA would be moved and subsumed by another CBSA in CY 2025. Table 30 lists the CBSAs that, under our proposal to adopt the revised OMB statistical area delineations, would be subsumed by another CBSA.

TABLE 30: URBAN AREAS THAT WOULD BE SUBSUMED BY ANOTHER CBSA

Current CBSA Code	Current CBSA Name	Proposed CY 2025 CBSA Code	Proposed CY 2025 CBSA Name
31460	Madera, CA	23420	Fresno, CA
36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
41900	San Germán, PR	32420	Mayagüez, PR

In other cases, if we adopt the new OMB delineations, some counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. In another type of change, some CBSAs have counties that would split off to become part of, or to form entirely new labor market areas. For example, the District of Columbia, DC, Charles County, MD and Prince Georges County, MD would move from CBSA 47894 (Washington-Arlington-Alexandria, DC–VA–MD–WV) into CBSA 47764 (Washington, DC-MD). Calvert County, MD would move from CBSA 47894 (Washington-Arlington-Alexandria, DC–VA–MD–WV) into CBSA 30500 (Lexington Park, MD). The remaining counties that currently make up 47894 (Washington-Arlington-Alexandria, DC–VA–MD–WV) would move into CBSA 11694 (Arlington-Alexandria-Reston, VA–WV). Finally, in some cases, a CBSA would lose counties to another existing CBSA if we adopt the new OMB delineations. For example, Grainger County, TN would move from CBSA 34100 (Morristown, TN) into CBSA 28940 (Knoxville, TN). Table 31 lists the 73 urban counties that would move from one urban CBSA to a new or modified urban CBSA if we adopt the revised OMB delineations.

TABLE 31: COUNTIES THAT WOULD CHANGE TO A DIFFERENT URBAN CBSA

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CY 2025 CBSA	Proposed CY 2025 CBSA Name
13013	BARROW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13035	BUTTS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13045	CARROLL	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13063	CLAYTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13077	COWETA	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13085	DAWSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13089	DE KALB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13097	DOUGLAS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13113	FAYETTE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13117	FORSYTH	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13121	FULTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13135	GWINNETT	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13149	HEARD	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13151	HENRY	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13159	JASPER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13199	MERIWETHER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13211	MORGAN	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13217	NEWTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13227	PICKENS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13231	PIKE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13247	ROCKDALE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13255	SPALDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13297	WALTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13015	BARTOW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13057	CHEROKEE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13067	COBB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13143	HARALSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13223	PAULDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
21163	MEADE	KY	21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN
17097	LAKE	IL	29404	Lake County-Kenosha County, IL-WI	29404	Lake County, IL
55059	KENOSHA	WI	29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI
06039	MADERA	CA	31460	Madera, CA	23420	Fresno, CA
47057	GRAINGER	TN	34100	Morristown, TN	28940	Knoxville, TN
37019	BRUNSWICK	NC	34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	48900	Wilmington, NC
22103	ST. TAMMANY	LA	35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville-Covington, LA
34009	CAPE MAY	NJ	36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
72023	CABO ROJO	PR	41900	San Germán, PR	32420	Mayagüez, PR
72079	LAJAS	PR	41900	San Germán, PR	32420	Mayagüez, PR
72121	SABANA GRANDE	PR	41900	San Germán, PR	32420	Mayagüez, PR
72125	SAN GERMAN	PR	41900	San Germán, PR	32420	Mayagüez, PR
53061	SNOHOMISH	WA	42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA
25015	HAMPSHIRE	MA	44140	Springfield, MA	11200	Amherst Town-Northampton, MA
12103	PINELLAS	FL	45300	Tampa-St. Petersburg-Clearwater, FL	41304	St. Petersburg-Clearwater-Largo, FL
12053	HERNANDO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12057	HILLSBOROUGH	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name	Proposed CY 2025 CBSA	Proposed CY 2025 CBSA Name
12101	PASCO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
39123	OTTAWA	OH	45780	Toledo, OH	41780	Sandusky, OH
51013	ARLINGTON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51043	CLARKE	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51047	CULPEPER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51059	FAIRFAX	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51061	FAUQUIER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51107	LOUDOUN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51153	PRINCE WILLIAM	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51157	RAPPAHANNOCK	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51177	SPOTSYLVANIA	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51179	STAFFORD	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51187	WARREN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51510	ALEXANDRIA CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51600	FAIRFAX CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51610	FALLS CHURCH CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51630	FREDERICKSBURG CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51683	MANASSAS CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51685	MANASSAS PARK CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
54037	JEFFERSON	WV	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
11001	THE DISTRICT	DC	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24017	CHARLES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24033	PRINCE GEORGES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24009	CALVERT	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD
24037	ST. MARYS	MD	15680	California-Lexington Park, MD	30500	Lexington Park, MD
72059	GUAYANILLA	PR	49500	Yauco, PR	38660	Ponce, PR
72111	PENUELAS	PR	49500	Yauco, PR	38660	Ponce, PR
72153	YAUCO	PR	49500	Yauco, PR	38660	Ponce, PR

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f. Proposed Transition Period

In the past we have provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts, in order to mitigate the potential impacts of proposed home health policies. For example, we have proposed and finalized budget-neutral transition policies to help mitigate negative impacts on HHAs following the adoption of the new CBSA delineations based on the 2010 Decennial Census data in the CY 2015 HH PPS final rule (79 FR 66032). Specifically, we implemented a 1-year 50/50 blended wage to the new OMB delineations. We applied a blended wage index for 1 year (CY 2015) for all geographic areas that would consist of a 50/50 blend of the wage index values using OMB's old area delineations and the wage index values using OMB's new area delineations. That is, for each county, a blended wage index was calculated equal to 50 percent of the CY 2015 wage index using the old labor market area delineation and 50 percent of the CY 2015 wage index using the new labor market area delineation, which resulted in an average of the two values. Additionally, in the CY 2021 HH PPS final rule (85 FR 70312), we proposed and finalized a transition policy to apply a 5-percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior CY. This transition allowed the effects of our adoption of the revised CBSA delineations from OMB Bulletin 18–04 to be phased in over 2 years, where the estimated reduction in a geographic area's wage index was capped at five percent in CY 2021 (that is, no cap was applied to the reduction in the wage index for the second year (CY 2022)). We explained that we believed a 5-percent cap on the overall decrease in a geographic area's wage index value would be appropriate for CY 2021, as it provided predictability in payment levels from CY 2020 to CY 2021 and additional transparency because it was administratively simpler than our prior one-year 50/50 blended wage index approach.

In the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we adopted a permanent 5-percent cap on wage index decreases beginning in CY 2023 and each subsequent year. The policy applies a permanent 5-percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline, so that a geographic area's wage index would not be less than 95 percent of its wage index calculated in the prior CY.

For CY 2025, we believe that the permanent 5-percent cap on wage index decreases would be sufficient to mitigate any potential negative impact caused by adopting the revised OMB delineations and that no further transition is necessary. Previously, the 5-percent cap had been applied at the CBSA or statewide rural area level, meaning that all the counties that make up the CBSA or rural area received the 5-percent cap. However, for CY 2025, to mitigate any potential negative impact caused by the adoption of the revised delineations, we propose that in addition to the 5-percent cap being calculated for an entire CBSA or statewide rural, the cap would also be calculated at the county level, so that individual counties moving to a new delineation would not experience more than a 5 percent decrease in wage index from the previous calendar year. Specifically, we are proposing for CY 2025, that the 5-percent cap would also be applied to counties that would move from a CBSA or statewide rural area with a higher wage index value into a new CBSA or rural area with a lower wage index value, so that the county's CY 2025 wage index would not be less than 95 percent of the county's CY 2024 wage index value under the old delineation despite moving into a new delineation with a lower wage index.

Due to the way that we propose to calculate the 5-percent cap for counties that experience an OMB designation change, some CBSAs and statewide rural areas could have more than one wage index value because of the potential for their constituent counties to have different wage index values. Specifically, some counties that change OMB designations would have a wage index value that is different than the wage index value assigned to the other constituent counties that make up the CBSA or statewide rural area that they are moving into because of the application of the 5-percent cap. However, for home health claims processing, each CBSA or statewide rural area can have only one wage index value assigned to that CBSA or statewide rural area.

Therefore, HHAs that serve beneficiaries in a county that would receive the cap would need to use a number other than the CBSA or statewide rural area number to identify the county's appropriate wage index value on home health claims in CY 2025. We are proposing that beginning in CY 2025, counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5-percent cap would use a wage index transition code. These special codes are five digits in length and begin with ''50'' and the remaining digits are unique for that code. We are using Xs to show how the transition codes could be labeled. The 50XXX[9] wage index transition codes would be used only in specific counties; counties located in CBSAs and rural areas that do not correspond to a different transition wage index value will still use the CBSA number. For example, FIPS county 13171 Lamar County, GA is currently part of CBSA 12060 Atlanta-Sandy Springs-Alpharetta. However, for CY 2025 we are proposing that Lamar County would be redesignated into the Rural Georgia Code 99911. Because the wage index value of rural Georgia is more than a 5-percent decrease from the wage index value that Lamar County previously received under CBSA 12060, the CY 2025 wage index for Lamar County would be capped at 95 percent of the CY 2024 wage index value for CBSA 12060. Additionally, because rural Georgia can only have one wage index value assigned to code 99911, in order for Lamar County to receive the capped wage index for CY 2025, transition code 50003 would be used on a home health claim instead of rural Georgia code 99911.

We are also proposing that the 5-percent cap would apply to a county that corresponds to a different wage index value than the wage index value in the CBSA or rural area in which they are designated due to a delineation change until the county's new wage index is more than 95 percent of the wage index from the previous calendar year. Therefore, in order to capture the correct wage index value, an HHA would continue to use the assigned 50XXX transition code for the county until the county's wage index value calculated for that calendar year using the new OMB delineations is not less than 95 percent of the county's capped wage index from the previous calendar year. Thus, in the example mentioned earlier, claims for Lamar County would use transition code 50003 until the wage index in its revised designation of Rural Georgia is equal to or more than 95 percent of its wage index value from the previous calendar year. The counties that will require a transition code and the corresponding 50XXX codes are shown in table 32 and will also be shown in the last column of the CY 2025 HH PPS wage index file.

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[9] The remaining 3 characters of the code to be determined if finalized.

TABLE 32: COUNTIES THAT WOULD USE A WAGE INDEX TRANSITION CODE

County Name	State	CY 2024 CBSA	CY 2024 CBSA Name	Proposed CY 2025 CBSA	Proposed CY 2025 CBSA Name	Transition Code
WASHINGTON	AL	33660	Mobile, AL	99901	ALABAMA	50001
FRANKLIN	AR	22900	Fort Smith, AR-OK	99904	ARKANSAS	50002
LAMAR	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	99911	GEORGIA	50003
KALAWAO	HI	99912	HAWAII	27980	Kahului-Wailuku, HI	50004
POWER	ID	38540	Pocatello, ID	99913	IDAHO	50005
VERMILION	IL	19180	Danville, IL	99914	ILLINOIS	50006
PUTNAM	IN	26900	Indianapolis-Carmel-Anderson, IN	99915	INDIANA	50007
HENDERSON	KY	21780	Evansville, IN-KY	99918	KENTUCKY	50008
IBERIA	LA	29180	Lafayettc, LA	99919	LOUISIANA	50009
CALVERT	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD	50010
WORCESTER	MD	41540	Salisbury, MD-DE	99921	MARYLAND	50011
FRANKLIN	MA	44140	Springfield, MA	99922	MASSACHUSETTS	50012
SHIAWASSEE	MI	29620	Lansing-East Lansing, MI	99923	MICHIGAN	50013
LAKE	MN	20260	Duluth, MN-WI	99924	MINNESOTA	50014
ROCK	MN	99924	MINNESOTA	43620	Sioux Falls, SD-MN	50015
LYON	NV	99929	NEVADA	39900	Reno, NV	50016
YATES	NY	40380	Rochester, NY	99933	NEW YORK	50017
GRANVILLE	NC	20500	Durham-Chapel Hill, NC	99934	NORTH CAROLINA	50018
HAYWOOD	NC	11700	Asheville, NC	99934	NORTH CAROLINA	50019
OTTAWA	OH	45780	Toledo, OH	41780	Sandusky, OH	50020
PIKE	PA	35084	Newark, NJ-PA	99939	PENNSYLVANIA	50021
MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	99949	VIRGINIA	50022
SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC	99949	VIRGINIA	50023
FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC	99949	VIRGINIA	50023
JACKSON	WV	16620	Charleston, WV	99951	WEST VIRGINIA	50024
LINCOLN	WV	16620	Charleston, WV	99951	WEST VIRGINIA	50024
MINERAL	WV	19060	Cumberland, MD-WV	99951	WEST VIRGINIA	50025
ADJUNTAS	PR	38660	Ponce, PR	99940	PUERTO RICO	50026
CABO ROJO	PR	41900	San Germán, PR	32420	Mayagüez, PR	50027
GUANICA	PR	49500	Yauco, PR	99940	PUERTO RICO	50028
LAJAS	PR	41900	San Germán, PR	32420	Mayagüez, PR	50027
LARES	PR	10380	Aguadilla-Isabela, PR	99940	PUERTO RICO	50029
LAS MARIAS	PR	32420	Mayagüez, PR	99940	PUERTO RICO	50028
SABANA GRANDE	PR	41900	San Germán, PR	32420	Mayagüez, PR	50027
SAN GERMAN	PR	41900	San Germán, PR	32420	Mayagüez, PR	50027
UTUADO	PR	10380	Aguadilla-Isabela, PR	99940	PUERTO RICO	50029

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The proposed wage index file applicable to CY 2025 provides a crosswalk between the CY 2025 wage index using the current OMB delineations and the CY 2025 wage index using the proposed revised OMB delineations that would be in effect in CY 2025 if these proposed changes are finalized. This file shows each state and county and its corresponding proposed wage index along with the previous CBSA number, the proposed CBSA number or proposed transition code, and the proposed CBSA name. The proposed HH PPS wage index file applicable for CY 2025 (January 1, 2025, through December 31, 2025) is available on the CMS website at: *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.*

3. Proposed CY 2025 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 health payments. We propose to continue this practice for CY 2025, as it is our belief that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data, including any changes made by the Office of Management and Budget (OMB) to Metropolitan Statistical Area (MSA) definitions, is appropriate and reasonable for the HH PPS. The appropriate wage index value is applied 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).

For CY 2025, we propose to base the HH PPS wage index on the FY 2025 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021 (FY 2021 cost report data), with the revised OMB delineations. The proposed CY 2025 HH PPS wage index would not take into account any geographic reclassification of hospitals, including those in accordance with section 1886(d)(8)(B) or 1886(d)(10) of the Act but would include the 5-percent cap on wage index decreases.

There exist some geographic areas where there are no hospitals, and thus, no hospital wage data on which to base the calculation of the HH PPS wage index. 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 2025 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 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 2025, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). Using the average wage index of all urban areas in Georgia as a proxy, we propose the CY 2025 wage index value for Hinesville, GA, would be 0.8608.

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. The term ''contiguous'' means sharing a border (72 FR 49859). For CY 2025, as part of our proposal to adopt the revised OMB delineations discussed further in section III.E.2. of this proposed rule, we are proposing that rural North Dakota would now become a rural area without a hospital from which hospital wage data can be derived. Therefore, in order to calculate the wage index for rural area 99935, North Dakota, we are proposing to use as a proxy, the average pre-floor, pre-reclassified hospital wage data from the contiguous CBSAs: CBSA 13900-Bismark, ND, CBSA 22020-Fargo, ND–MN, CBSA 24220-Grand Forks, ND–MN, and CBSA 33500, Minot, ND, which results in a proposed CY 2025 HH PPS wage index of 0.8334 for rural North Dakota.

TABLE 33: CY 2025 WAGE INDEX FOR RURAL NORTH DAKOTA

CBSA Code	CBSA Name	CY 2025 HH PPS Wage Index
13900	Bismarck, ND	0.9020
22020	Fargo, ND-MN	0.8763
24220	Grand Forks, ND-MN	0.7865
33500	Minot, ND	0.7686
	Proposed CY 2025 HH PPS Wage Index	**0.8334**

Previously, the only rural area without a hospital from which hospital wage data could be derived was in Puerto Rico. However, for rural Puerto Rico, we did not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the proximity of 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 used the most recent wage index previously available for that area, which was 0.4047. For CY 2025, due to our proposal to adopt the revised OMB delineations discussed previously, there is now a hospital in rural Puerto Rico from which hospital wage data can be derived. Therefore, we are proposing that the wage index for rural Puerto Rico would now be based on the hospital wage data for the area instead of the previously available wage index of 0.4047. The unadjusted CY 2025 proposed wage index for rural Puerto Rico would equal 0.2520. However, because 0.2520 is more than a 5 percent decline in the CY 2024 wage index, the 5-percent cap would be applied. We are proposing that the CY 2025 5-percent cap adjusted wage index for rural Puerto Rico would be set equal to 95 percent of the CY 2024 wage index, which results in a proposed wage index value of 0.3845.

Finally, due to the proposal to adopt the revised OMB delineations, Delaware, which was previously an all-urban state, would now have one rural area with a hospital from which hospital wage data can be derived. As such, the proposed CY 2025 wage index for rural Delaware would be 1.0429.

The complete proposed CY 2025 wage index is available on the CMS website at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

4. Proposed CY 2025 Home Health Payment Update

a. 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 2024 HH PPS final rule (88 FR 77676), we finalized the rebasing of the home health market basket to reflect 2021 Medicare cost report data. We also finalized that for CY 2024 and subsequent years the labor-related share would be 74.9 percent and the non-labor-related share would be 25.1 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2025:

- 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 (74.9 percent) and a non-labor portion (25.1 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 percentage, 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 partial payment 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.

(b) CY 2025 National, Standardized 30-Day Period Payment Amount

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 2025 national, standardized 30-day period payment rate, we will continue our practice of using the most recent, complete utilization data at the time of rulemaking; that is, we are using CY 2023 claims data for CY 2025 payment rate updates. We apply a permanent adjustment factor, a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, and the home health payment update percentage to update the CY 2025 payment rate. As discussed in section II.C.1. of this proposed rule, we are proposing to implement a permanent adjustment of −4.067 percent to ensure that payments under the PDGM do not exceed what payments would have been under the 153-group payment system as required by law. The proposed permanent adjustment factor is 0.95933. 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 weight budget neutrality factor to the CY 2025 national, standardized 30-day period payment rate. The proposed case-mix weight budget neutrality factor for CY 2025 is 1.0035.

Additionally, we apply a wage index budget neutrality factor to ensure that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day periods using the CY 2025 wage index (with the proposed revised delineations and the 5-percent cap) so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2024 wage index (with the old delineations and the 5-percent cap) and the CY 2024 national standardized 30-day period payment rate adjusted by the case-mix weights recalibration neutrality factor. Then, by dividing the payment rate for non-LUPA 30-day periods using the CY 2025 wage index (with the proposed revised delineations and a 5-percent cap on wage index decreases) by the payment rate for non-LUPA 30-day periods using the CY 2024 wage index (with the old delineations and a 5-percent cap on wage index decreases), we obtain a wage index budget neutrality factor of 0.9985. We then apply the wage index budget neutrality factor of 0.9985 to the 30-day period payment rate.

Next, we propose to update the 30-day period payment rate by the proposed CY 2025 home health payment update percentage of 2.5 percent. The CY 2025 national standardized 30-day period payment rate is calculated in table 34.

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TABLE 34: CY 2025 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2024 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	Case-Mix Weights Recalibration Budget Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor	CY 2025 National, Standardized 30-Day Period Payment
$2,038.13	0.95933	1.0035	0.9985	1.025	$2,008.12

The CY 2025 national standardized 30-day period payment rate for an HHA that does not submit the required quality data is updated by the proposed CY 2025 home health payment update percentage of 0.5 percent (2.5 percent minus 2 percentage points) and is shown in table 35.

TABLE 35: CY 2025 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAs THAT DO NOT SUBMIT THE QUALITY DATA

CY 2024 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	Case-Mix Weights Recalibration Neutrality Factor	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor Minus 2 Percentage Points	CY 2025 National, Standardized 30-Day Period Payment
$2,038.13	0.95933	1.0035	0.9985	1.005	$1,968.94

c. CY 2025 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 home health discipline. The six home health 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 proposed CY 2025 national per-visit rates, we started with the CY 2024 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 2025 wage index with the new delineations and the 5-percent cap on wage index decreases and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2024 wage index with the old delineations and the 5-percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2025 wage index by the total payments for LUPA 30-day periods of care using the CY 2024 wage index, we obtained a wage index budget neutrality factor of 0.9991. We apply the wage index budget neutrality factor in order to calculate the CY 2025 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Additionally, we are not applying the permanent adjustment to the per visit payment rates but only to the case-mix adjusted 30-day payment rate. Lastly, the per-visit rates for each discipline are updated by the proposed CY 2025 home health payment update percentage of 2.5 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 2025 national per-visit rates for HHAs that submit the required quality data are updated by the proposed CY 2025 home health payment update percentage of 2.5 percent and are shown in table 36.

TABLE 36: CY 2025 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2024 Per-Visit Payment Amount	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor	CY 2025 Per-Visit Payment Amount
Home Health Aide	$76.23	0.9991	1.025	$78.07
Medical Social Services	$269.87	0.9991	1.025	$276.37
Occupational Therapy	$185.29	0.9991	1.025	$189.75
Physical Therapy	$184.03	0.9991	1.025	$188.46
Skilled Nursing	$168.37	0.9991	1.025	$172.42
Speech-Language Pathology	$200.04	0.9991	1.025	$204.86

The CY 2025 per-visit payment rates for HHAs that do not submit the required quality data are updated by the proposed CY 2025 home health payment update percentage of 2.5 percent minus 2 percentage points and are shown in table 37.

TABLE 37: CY 2024 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAs THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2024 Per-Visit Payment Amount	Wage Index Budget Neutrality Factor	CY 2025 HH Payment Update Factor Minus 2 Percentage Points	CY 2025 Per-Visit Payment Amount
Home Health Aide	$76.23	0.9991	1.005	$76.54
Medical Social Services	$269.87	0.9991	1.005	$270.98
Occupational Therapy	$185.29	0.9991	1.005	$186.05
Physical Therapy	$184.03	0.9991	1.005	$184.78
Skilled Nursing	$168.37	0.9991	1.005	$169.06
Speech-Language Pathology	$200.04	0.9991	1.005	$200.86

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d. 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, whereby we finalized the approach of multiplying the per-visit payment amount for the first skilled nursing (SN), physical therapy (PT), or speech language pathology (SLP) visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by 1 + the proportional increase in minutes for an initial visit over non-initial visits. Specifically, we updated the analysis using 100 percent of LUPA episodes and a 20 percent sample of non-LUPA first episodes from CY 2012 claims data. The analysis showed that the average excess of minutes for the first visit in LUPA episodes that were the only episode or an initial LUPA in a sequence of adjacent episodes are 37.27 minutes for the first visit if SN, 31.69 minutes for the first visit if PT, and 31.56 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes were 44.10 minutes for SN, 47.30 minutes for PT, and 50.37 minutes for SLP. To determine the final LUPA add-on factors for each discipline, we calculated the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. (Of note, the average excess minutes for the first visit in LUPA add-on claims equal, for each discipline, is equal to the average minutes for the first visit in LUPA add-on claims minus the average minutes for non-first visits in LUPA add-on claims.) We then added one to these ratios to obtain the respective finalized add on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. 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 SN, PT, or SLP 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 (using the already established LUPA add-on factors of 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.

At this time, in an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, CMS is proposing to update the LUPA add-on factors for PT, SN, and SLP, which have not been revised since the CY 2014 HH PPS final rule, during which CY 2012 data was used. For this proposed rule, we are proposing to use the same methodology used to establish the LUPA add-on amount for CY 2014, using updated claims data.

Specifically, we are proposing to update the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. In doing so, the analysis demonstrates that the average excess of minutes for the first visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods are 30.00 minutes for the first visit if SN, 28.18 minutes for the first visit if PT, and 31.59 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes are 41.51 minutes for SN, 45.11 minutes for PT, and 47.13 minutes for SLP. The following table 38 shows the average excess minutes for the first visit in LUPA periods, the average minutes for all non-first visits in non-LUPA episodes, as well as the current LUPA add-on factors, the proposed LUPA add-on factors, and the percent change between the current and the proposed LUPA add-on factors. This table also shows the proposed OT LUPA add-on factor outlined in section II.4.e. of this proposed rule as follows:

TABLE 38: CURRENT AND PROPOSED LUPA ADD-ON FACTORS

Discipline	Current LUPA Add-on Factors	Proposed LUPA Add-on Factors Using Data from CY2023	Percent Change from Old to New	Average Excess of Minutes for the First Visit in LUPA Periods	Average Minutes for All Non-First Visits in Non-LUPA Episodes
SN	1.8451	1.7227	-6.6%	30.00	41.51
PT	1.6700	1.6247	-2.7%	28.18	45.11
SLP	1.6266	1.6703	+2.7%	31.59	47.13
OT	1.6700	1.7266	+3.4%	33.40	45.97

To determine the LUPA add-on factors for each discipline in relation to the aforementioned proposed LUPA add-on factor updates, we calculate the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then add one to these ratios to obtain the proposed add on factors: 1.7227 for SN; 1.6247 for PT; and 1.6703 for SLP. As an example of the application of the proposed add-on factors for CY 2025, for LUPA periods that occur as the only episode or an initial period in a sequence of adjacent periods, if the first skilled visit is SN, the payment for that visit would be $297.03 (1.7227 multiplied by $172.42). The proposed LUPA add-on factors will be updated based on more complete CY 2023 claims data in the final rule. As such, we solicit comments on the proposals to update the LUPA factors using the 2014 methodology and based on these updated numbers, re-price the LUPA payment amounts.

e. Occupational Therapy LUPA Add-On Factor

In order to implement Division CC, section 115, of the Consolidation Appropriations Act (CAA), 2021, CMS finalized changes to regulations at § 484.55(a)(2) and (b)(3) that allowed occupational therapists 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 included OT, as well as either PT or SLP (86 FR 62351). This change necessitated the establishment of a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT 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. However, at the time of the implementation, as we stated in the CY 2022 HH PPS final rule (86 FR 62289), there was not sufficient data regarding the average excess of minutes for the first visit in LUPA periods when the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we finalized that we would use the PT LUPA add-on factor of 1.6700 as a proxy. We also stated in the CY 2022 final rule that we would use the PT LUPA add-on factor 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 (86 FR 62289). Ultimately, we refrained from using CY 2022 data (and instead utilized the PT LUPA add-on factor as a proxy for the OT LUPA add-on factor), as we marked the first year that occupational therapists were permitted to conduct the initial assessment. Therefore, we wanted to extend our analysis to ensure we had sufficient data to reflect OT time spent conducting initial assessments to establish a discrete OT LUPA add-on factor (86 FR 62240). Accordingly, we continued analyzing claims data and have opted to utilize CY 2023 data to make this proposal.

With sufficient recent claims data available, and to establish equitable compensation for all home health services, CMS is now proposing to establish a definitive OT-specific LUPA add-on factor and discontinue the temporary use of the PT LUPA add-on factor as a proxy. For this proposal, we are using the same methodology used to establish the LUPA add-on amount for CY 2014, as also described previously for the SN, PT and SLP add-on factors. Specifically, we are updating the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. The analysis shows that the average excess of minutes for the first OT visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods is 33.40 minutes for the first visit. The average number of minutes for all non-first visits in non-LUPA periods is 45.97 minutes for OT.

To determine the LUPA add-on factors for OT to adequately adjust LUPA payments to account for the excess minutes during the first visit in a LUPA period, we are proposing to calculate the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We are proposing to then add one to this ratio to obtain the proposed add on factor: 1.7266 for OT. As an example of the application of the proposed add-on factor, for LUPA periods that occur as the only period or as an initial period in a sequence of adjacent periods, if the first skilled visit is OT, the payment for that visit will be $327.62 (1.7266 multiplied by $189.75). Table 38 shows the current LUPA add-on factors and the proposed LUPA add-on factors. The proposed OT LUPA add-on factor will be updated based on more complete CY 2023 claims data in the final rule. As such, we solicit comments on the proposed use of OT data to determine the OT LUPA add-on factor, as well as the proposed methodology to determine this OT LUPA add-on factor.

f. 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 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 maintaining 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 propose a change to the FDL ratio for CY 2021. In the CY 2022 HH PPS final rule with comment period (86 FR 62292), we estimated that outlier payments would be approximately 1.8 percent of total HH PPS final rule payments if we maintained an FDL of 0.56 in CY 2022. Therefore, in order to pay up to, but no more than, 2.5 percent of total payments as outlier payments we finalized an FDL of 0.40 for CY 2022. In the CY 2023 HH PPS final rule (87 FR 66875), using CY 2021 claims utilization data, we finalized an FDL of 0.35 in order to pay up to, but no more than, 2.5 percent of the total payment as outlier payments in CY 2023. In the CY 2024 HH PPS final rule (88 FR 77749), using CY 2022 claims utilization data, we finalized an FDL of 0.27 for CY 2024.

(2) Proposed FDL Ratio for CY 2025

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 2023 claims data (as of March 19, 2024) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are proposing an FDL ratio of 0.38 for CY 2025 which is higher than the finalized CY 2024 FDL of 0.27. CMS will update the FDL, if needed, in the final rule once we have more complete CY 2023 claims data.

F. Annual Rate Update for Disposable Negative Pressure Wound Therapy (dNPWT) Device

1. Background

Negative pressure wound therapy (NPWT) is a medical procedure in which a vacuum dressing is used to enhance and promote healing in acute, chronic, and burn wounds. The therapy

involves using a sealed wound dressing attached to a pump to create a negative pressure environment in the wound. The therapy can be administered using the conventional NPWT system, classified as durable medical equipment (DME), or can be administered using a disposable device. A disposable NPWT (dNPWT) device is a single-use integrated system that consists of a non-manual vacuum pump, a receptacle for collecting exudate, and wound dressings. Unlike conventional NPWT systems classified as DME, dNPWT devices have preset continuous negative pressure, no intermittent setting, are pocket-sized and easily transportable, and are generally battery-operated with disposable batteries. In order for a beneficiary to receive dNPWT under the home health benefit, the beneficiary must qualify for the home health benefit in accordance with existing eligibility requirements.

2. Payment Policies for dNPWT Devices

Prior to CY 2024, the separate payment amount for dNPWT included the furnishing of services as well as the dNPWT device. The separate payment amount was set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the CPT codes 97607 and 97608. Payment for visits where the sole purpose of a home health visit was to furnish dNPWT was not made under the HH PPS. Therefore, visits performed solely for the purpose of furnishing a new dNPWT device were not reported on the HH PPS claim (TOB 32x), instead HHAs submitted these claims on a TOB 34x. However, if a home health visit included the provision of other home health services in addition to, and separate from, furnishing dNPWT, the HHA submitted both a TOB 32x and TOB 34x—the TOB 32x for other home health services and the TOB 34x for furnishing NPWT using a disposable device.

Beginning in CY 2024, Division FF, section 4136 of the CAA, 2023 (Pub. L. 117–328) amended section 1834 of the Act (42 U.S.C. 1395m(s)) and mandated several amendments to the Medicare separate payment for dNPWT. These changes included—

- For CY 2024, the separate payment amount for an applicable dNPWT device was set equal to the supply price used to determine the relative value for the service under the Physician Fee Schedule (PFS) under section 1848 as of January 1, 2022 (CY 2022), updated by the percent increase in the CPI–U for the 12-month period ending with June of the preceding year reduced by m the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act for such year;
- For 2025 and each subsequent year, the separate payment amount was to be set equal to the payment amount established for the device in the previous year, updated by the percent increase in the CPI–U for the 12-month period ending with June of the preceding year reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) for such year.
- The separate payment amount for applicable devices furnished on or after January 1, 2024, would no longer include payment for nursing or therapy services described in section 1861(m) of the Act so that payment for such nursing or therapy services are now made under the HH PPS, and is no longer separately billable.
- Claims for the separate payment amount of an applicable dNPWT device are now accepted and processed on claims submitted using the type of bill (TOB) 32X.

In the CY 2024 HH PPS final rule (88 FR 77676), we finalized our proposal to codify these changes to dNPWT payments mandated by the CAA, 2023. Beginning January 1, 2024, the separate payment for a dNPWT device is made to an HHA for an individual who is under a home health plan of care using Healthcare Common Procedure Coding System (HCPCS) code A9272. The code HCPCS A9272 is defined as a wound suction, disposable, includes dressing, all accessories and components, any type, each. The HHA reports the HCPCS code A9272 for the device only on the home health TOB 32X. The services related to the application of the device are included in the home health payment and are excluded from the separate payment amount for the device. The CY 2024 single payment amount for a dNPWT device for individuals under a home health plan of care was set equal to $270.09, which equaled the supply price of an applicable device under the Medicare PFS (as of January 1, 2022) of $263.25 updated by the 2.6 percent increase in the CPI–U for the 12-month period ending in June of 2023, minus the productivity adjustment.

3. CY 2025 Separate Payment Amount for dNPWT Device

For CY 2025, we are proposing that the separate payment amount for a dNPWT device would be set equal to the CY 2024 payment amount of $270.09 updated by the CPI–U for June 2024, minus the productivity adjustment, as mandated by the CAA, 2023. The application of the productivity adjustment may result in a net update that may be less than 0.0 for a year and may result in the separate payment amount for an applicable device for a year being less than such separate payment amount for such device for the preceding year. We note that the CPI–U for the 12-month period ending in June of 2024 is not available at the time of this proposed rulemaking. Therefore, the CY 2025 payment amount, as well as the CPI–U for the 12-month period ending in June of 2024, and the corresponding productivity adjustment will be updated in the final rule.

For CY 2026 and subsequent years, if CMS does not intend to propose changes to its established methodology for calculating dNPWT payments, payment rates will be updated using CMS's established methodology via the Home Health Prospective Payment System Rate Update Change Request and posted on the HHA Center website at *https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.* For more in-depth information regarding the finalized policies associated with the scope of the payment for dNPWT and conditions for payment, we refer readers to the CY 2024 HH PPS final rule (88 FR 77749 through 77752).

III. Home Health Quality Reporting Program (HH QRP)

A. 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 home health agency (HHA) submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data 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, as further reduced by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP 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. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890 of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the HH QRP. The HH QRP regulations can be found at 42 CFR 484.245 and 484.250.

Based on feedback from patients and stakeholders, CMS has launched an effort to update and shorten the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey. In 2023 CMS tested a shortened survey across a variety of different types of HHAs. We are reviewing the findings of the field test and plan to propose in the future updates to the survey with the intent to shorten it.

B. Summary of the Provision of This Proposed Rule

In this proposed rule, we are proposing to add four new items and to modify one assessment item on the OASIS. Second, we propose an update to the removal of the suspension of OASIS all-payer data collection. Third, we are seeking information on future HH QRP quality measure concepts. These proposals are further specified in the following sections.

For a detailed discussion of the considerations, we historically use for measure selection for the HH QRP quality, resource use, and other 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 period (83 FR 56548 through 56550) we finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2024 HH QRP

The HH QRP currently includes 21 measures for the CY 2024 program year, as described in table 39.

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TABLE 39: MEASURES CURRENTLY ADOPTED FOR THE CY 2024 HH QRP

Short Name	Measure Name & Data Source
QM Name	**OASIS-based**
Ambulation	Improvement in Ambulation/Locomotion (CBE #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #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 (CBE #2631).[4]
Bathing	Improvement in Bathing (CBE #0174).
Bed Transferring	Improvement in Bed Transferring (CBE # 0175).
Patient COVID-19 Vaccination	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
DC Function	Discharge Function Score
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (CBE #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation Of Care (CBE #0526).
TOH -Provider	Transfer of Health Information to Provider-Post-Acute Care[1]
TOH -Patient	Transfer of Health Information to Patient-Post-Acute Care[1]
QM Name	**Claims-based**
ACH	Acute Care Hospitalization During the First 60 Days of HH (CBE #0171)[3]
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (CBE #3477)
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of HH (CBE #0173)[3]
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.
PPH	Home Health Within Stay Potentially Preventable Hospitalization
QM Name	**HHCAHPS-based**
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (CBE #0517)[2] - 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.

NOTES: 1. Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider. 2. The HHCAHPS has five components that together are used to represent one CBE-endorsed measure. 3. ACH and ED Use will be retired from public reporting in October 2024 4. Application of Functional Assessment will be retired from public reporting in January 2025.

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D. Proposal To Collect Four New Items as Standardized Patient Assessment Data Elements and Modify One Item Collected as a Standardized Patient Assessment Data Element Beginning With the CY 2027 HH QRP

In this proposed rule, we are proposing to add four new items [10] to be collected as standardized patient assessment data elements under the social determinants of health (SDOH) category HH QRP: Living Situation (one item); Food (two items); and Utilities (one item). We are also proposing to modify one of the current items collected as standardized patient assessment data under the SDOH category (the Transportation item) as described in section III.D.5. of this proposed rule.

1. Definition of Standardized Patient Assessment Data

Section 1895(b)(3)(B)(v) of the Act requires that for CY 2007 and subsequent years, HHAs submit quality data to the Secretary. Section 1899B(a)(1)(C) of the Act requires, in part, the Secretary to modify the post-acute care (PAC) assessment instruments for PAC providers, including HHAs, to submit standardized patient assessment data under the Medicare program. Section 1899B(b)(1)(A) of the Act requires PAC providers to submit standardized patient assessment data under applicable reporting provisions (which, for HHAs, is the HH QRP) for the admission (start and resumption of care) and discharge of an individual (and more frequently as the Secretary deems appropriate). Section1899B(b)(1)(B) of the Act defines standardized patient assessment data as data required for at least the quality measures described in section 1899B(c)(1) of the Act and that is concerning the following categories: (1) functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow, and (6) other categories deemed necessary and appropriate by the Secretary.

2. Social Determinants of Health (SDOH) Collected as Standardized Patient Assessment Data Elements

Section 1899B(b)(1)(B)(vi) of the Act authorizes the Secretary to collect standardized patient assessment data elements with respect to other categories deemed necessary and appropriate. Accordingly, we finalized the creation of the SDOH category of standardized patient assessment data elements in the CY 2020 HH PPS final rule (84 FR 60597 through 60608). SDOH are the socioeconomic, cultural, and environmental circumstances in which individuals live that impact their health.[11] According to the World Health Organization research shows that the SDOH can be more important than health care or lifestyle choices in influencing health, accounting for between 30–55% of health outcomes.[12] This is a part of a growing body of research that highlights the importance of SDOH on health outcomes. Subsequent to the CY 2020 HH PPS final rule, we expanded our definition of SDOH: SDOH are the conditions in the environments where people are born, live, learn, work, play, worship and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[13] [14] [15] This expanded definition aligns our definition of SDOH with the definition used by HHS agencies, including OASH, the Centers for Disease Control and Prevention (CDC) and the White House Office of Science and Technology Policy.[16] [17] We currently collect seven items in this SDOH category of standardized patient assessment data elements: ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation (84 FR 60597 through 60608).[18] In accordance with our authority under section 1899B(b)(1)(B)(vi) of the Act, we similarly finalized the creation of the SDOH category of standardized patient assessment data elements for skilled nursing facilities (SNFs) in the FY 2020 SNF PPS final rule (84 FR 38805 through 38817), for Inpatient Rehabilitation Facilities (IRFs) in the FY 2020 IRF PPS final rule (84 FR 39149 through 39161), and for Long Term Acute Hospitals (LTCHs) in the FY 2020 LTCH PPS final rule (84 FR 42577 through 42579). We also collect the same seven SDOH items in these PAC providers' respective patient/resident assessment instruments (84 FR 38817, 39161, and 42577, respectively).

Adding access to standardized data relating to SDOH on a national level permits us to conduct periodic analyses, and to assess their appropriateness as risk adjustors or in future quality measures. Our ability to perform these analyses and to make adjustments relies on existing data collection of SDOH items from PAC settings. We adopted these SDOH items using common standards and definitions across the four PAC providers to promote interoperable exchange of longitudinal information among these PAC providers, including HHAs, and other providers. We believe this information may facilitate coordinated care, improve patient focused care planning, and allow for continuity of the discharge planning process from PAC settings.

We noted in our CY 2020 HH PPS final rule that each of the items was identified in the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report as impacting care use, cost, and outcomes for Medicare beneficiaries (84 FR 60598 through 60602). At that time, we acknowledged that other items may also be useful to understand. The SDOH items we are proposing to collect as standardized patient assessment data elements under the SDOH category in this proposed rule were also identified

[10] Items may also be referred to as ''data elements.''

[11] Office of the Assistant Secretary for Planning and Evaluation (ASPE). Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 28, 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs.*

[12] World health Organization. Social determinants of health. Available at: *https://www.who.inte/health-topics/social-determinants-of-health#tab=tab_1.*

[13] Using Z Codes: The Social Determinants of Health (SDOH). Data Journey to Better Outcomes.

[14] Improving the Collection of Social Determinants of Health (SDOH) Data with ICD–10–CM Z Codes. *https://www.cms.gov/files/document/cms-2023-omh-z-code-resource.pdf.*

[15] *CMS.gov* Measures Management System (MMS). CMS Focus on Health Equity. Health Equity Terminology and Quality Measures. *https://mmshub.cms.gov/about-qulaity-quality-at-CMS/goals/cms-focus-on-health-equity/health-equity-terminology.*

[16] Centers for Disease Control and Prevention. Social Determinants of Health (SDOH) and PLACES Data.

[17] ''U.S. Playbook to Address Social Determinants of Health'' from the White House Office Of Science And Technology Policy (November 2023).

[18] These SDOH data are also collected for purposes outlined in section 2(d)(2)(B) of the Improving Medicare Post-Acute Care Transitions Act (IMPACT Act). For a detailed discussion on SDOH data collection under section 2(d)(2)(B) of the IMPACT Act, see the CY 2020 HH PPS final rule (84 FR 60597 through 60608).

in the 2016 NASEM report [19] or the 2020 NASEM report [20] as impacting care use, cost and outcomes for Medicare beneficiaries. These items have the potential to affect treatment preferences and goals of patients and their caregivers. Identification of the SDOH items may also help HHAs be in a position to offer assistance, by connecting patients and their caregivers with these associated needs to social support programs, as well as inform our understanding of patient complexity.

Health-related social needs (HRSNs) are the resulting effects of SDOH, which are individual-level, adverse social conditions that negatively impact a person's health or health care.[21] Examples of HRSN include lack of access to food, housing, or transportation, and these have been associated with poorer health outcomes, greater use of emergency departments and hospitals, and higher health care costs.[22] [23] Certain HRSNs can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.[24] This is particularly true for food security, housing stability, utilities security, and access to transportation.[25] Evidence supports the positive impact on health outcomes of interventions aimed at addressing HRSNs.[26]

We are proposing to require HHAs collect and submit four new items in the OASIS as standardized patient assessment data elements under the SDOH category because these items would collect information not already captured by the current SDOH items. Specifically, we believe the ongoing identification of SDOH would have three significant benefits. First, promoting screening for SDOH could serve as evidence-based building blocks for supporting healthcare providers in actualizing their commitment to address disparities that disproportionately impact underserved communities. Second, screening for SDOH advances health equity through identifying potential social needs so the HHA may address those with the patient, their caregivers, and community partners during the home health episode and discharge planning process, if indicated.[27] Third, these SDOH items would support ongoing HH QRP initiatives by providing data with which to stratify HHAs' performance on current and future quality measures to improve care quality across different populations.

Additional collection of SDOH items would permit us to continue developing the statistical tools necessary to maximize the value of Medicare data and improve the quality of care for all beneficiaries. For example, we recently developed and released the Health Equity Confidential Feedback Reports, which provided data to HHAs on whether differences in quality measure outcomes are present for their patients by dual-enrollment status and race and ethnicity.[28] We note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars [29] and a Biden-Harris Administration priority.[30]

3. Proposal to Collect Four New Items as Standardized Patient Assessment Data Elements Beginning January 1, 2027, for the CY 2027 HH QRP Program Year [31]

We are proposing to require HHAs collect four new items as standardized patient assessment data elements under the SDOH category using the OASIS: one item for living situation, as described in III.D.3.a. of this proposed rule; two items for food, as described in section III.D.3.b. of this proposed rule; and one item for utilities, as described in section III.D.3.c of this proposed rule.

We selected the proposed SDOH items from the Accountable Health Communities (AHC) HRSN Screening Tool developed for the AHC Model. The AHC HRSN Screening Tool is a universal, comprehensive screening for HRSNs that was developed by a technical expert panel (TEP) in July 2016 to discuss opportunities and challenges involved in screening for HRSNs, consider and pare down CMS' list of evidence-based screening questions, and recommend a short list of questions for inclusion in the final tool.[32] [33] The TEP agreed to prioritize the inclusion of five SDOH domains as follows: (1) housing instability (for example, homelessness, poor housing quality); (2) food insecurity; (3) transportation difficulties; (4) utility assistance needs; and (5) interpersonal safety concerns (for example, intimate-

[19] Social Determinants of Health. Healthy People 2020. *https://www.healthypeople.gov/2020/gopics-objectives/topic/social-determinnats-of-health.* February 2019.

[20] National Academies of Sciences, Engineering, and Medicine. 2020. Leading Health Indicators 2030: Advancing Health, Equity, and Well-Being. Washington, DC: The National Academies Press. *https://doi.org/1017226/25682.*

[21] Centers for Medicare & Medicaid Services. ''A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights.'' August 2022. Available at *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

[22] Berkowitz, S.A., T.P. Baggett, and S.T. Edwards, ''Addressing Health-Related Social Needs: Value-Based Care or Values-Based Care?'' Journal of General Internal Medicine, vol. 34, no. 9, 2019, pp. 1916–1918, *https://doi.org/10.1007/s11606-019-05087-3.*

[23] Whitman A, De Lew N, Chappel A, Aysola V, Zuckerman R, & Sommers B D. Addressing social determinants of health: Examples of successful evidence-based strategies and current federal efforts. ASPE (Assistant Secretary for Planning and Evaluation) Office of Health Policy. Report HP–2022–12 April 1, 2022. SDOH-Evidence-Review.pdf (hhs.gov). Accessed 3/1/2024.

[24] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/.*

[25] Hugh Alderwick and Laura M. Gottlieb, ''Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems: Milbank Quarterly,'' Milbank Memorial Fund, November 18, 2019, *https://www.milbank.org/quarterly/articles/meanings-and-misunderstandings-a-social-determinants-of-health-lexicon-for-health-care-systems/.*

[26] Whitman A, De Lew N, Chappel A, Aysola V, Zuckerman R, & Sommers B D. Addressing social determinants of health: Examples of successful evidence-based strategies and current federal efforts. ASPE (Assistant Secretary for Planning and Evaluation) Office of Health Policy. Report HP–2022–12 April 1, 2022. SDOH-Evidence-Review.pdf (*hhs.gov*). Accessed 5/29/2024.

[27] American Hospital Association (2020). Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

[28] In October 2023, we released two new annual Health Equity Confidential Feedback Reports to HHAs: The Discharge to Community (DTC) Health Equity Confidential Feedback Report and the Medicare Spending Per Beneficiary (MSPB) Health Equity Confidential Feedback Report. The PAC Health Equity Confidential Feedback Reports stratified the DTC and MSPB measures by dual-enrollment status and race/ethnicity. For more information on the Health Equity Confidential Feedback Reports, please refer to the Education and Outreach materials available here: *https://www.cms.gov/medicare/quality/snf-quality-reporting-program/training.*

[29] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go from Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms.*

[30] The White House. The Biden-Harris Administration Immediate Priorities. *https://www.whitehouse.gov/priorities/.*

[31] Per the authority for the OASIS assessment instrument under 1891(d)(1), Home Health Conditions of Participation [42 U.S.C. 1395bbb].

[32] Centers for Medicare & Medicaid Services. ''A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights.'' August 2022. Available at *https://www.cms.gov/priorities/innovation/media/document/ahcm-screeningtool-companion.*

[33] Billioux, A., K. Verlander, S. Anthony, and D. Alley. 2017. Standardized screening for health-related social needs in clinical settings: The accountable health communities screening tool. Discussion Paper, National Academy of Medicine, Washington, DC. *https://nam.edu/wp-content/uploads/2017/05/Standardized-Screening-for-Health-Related-Social-Needsin-Clinical-Settings.pdf.*

partner violence, elder abuse, child maltreatment).[34]

We believe that requiring HHAs to report new items that are currently included in the AHC HRSN Screening Tools would further standardize the screening of SDOH across patient assessment instruments and the various quality reporting programs. For example, our proposal would align, in part, with the requirements of the Hospital Inpatient Quality Reporting (IQR) Program and the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. As of January 2024, hospitals are required to report whether they have screened patients for the standardized SDOH categories of housing stability, food security, and access to transportation to meet the Hospital IQR Program requirements.[35] Beginning January 2025, IPFs will also be required to report whether they have screened patients for the same set of SDOH categories.[36] As we continue to standardize data collection across PAC settings, we believe using common standards and definitions for new items is important to ensure the interoperable exchange of longitudinal information between HHAs and other providers to facilitate coordinated care, continuity in care planning, and the discharge planning process.

In the following section we describe each of the four proposed items in more detail.

a. Living Situation

Healthy People 2030 prioritizes economic stability as a key SDOH, of which housing stability is a component.[37] [38] Lack of housing stability encompasses several challenges, such as having trouble paying rent, overcrowding, moving frequently, or spending the bulk of household income on housing.[39] These experiences may negatively affect physical health and make it harder to access health care. Lack of housing stability can also lead to homelessness, which is housing deprivation in its most severe form.[40] On a single night in 2023, roughly 653,100 people, or 20 out of every 10,000 people in the United States, were experiencing homelessness.''[41] Rates of chronic disease and premature mortality are higher among the unsheltered homeless relative to the sheltered.[42] Older adults (aged 65 years and older) have lower rates of experiencing any housing instability compared to younger people (8.8% versus 18.7%), but low-income older adults may be more at risk for housing instability if they lack the resources necessary to secure and/or maintain structurally sound housing.[43] Adults (aged 18–64 years) with disabilities experience challenges to securing stable housing including affordability and accessibility.[44] We believe that HHAs can use information obtained from the Living Situation assessment item during a patient's initial assessment as well as in discharge planning. For example, HH social workers can work with patients experiencing housing instability to ensure patients are referred to available community resources, such as supportive housing programs. HHAs could work in partnership with community care hubs and community-based organizations to establish new care transition workflows, including referral pathways, contracting mechanisms, data sharing strategies, and implementation training that can track both health and social needs outcomes to ensure unmet needs, such as housing, are successfully addressed through closed loop referrals and follow-up.[45] HHAs could also take action to help alleviate a patient's other related costs of living, like food, by referring patients to community-based organizations that would allow patients' additional resources to be allocated towards housing without sacrificing other needs.[46] Finally, HHAs could use the information obtained from the Living Situation assessment item to better coordinate with other PAC facilities and agencies during transitions of care, so that referrals to address a patient's housing stability are not lost during vulnerable transition periods.

Due to the potential negative impacts housing instability can have on a patient's health, we are proposing to adopt the Living Situation assessment item as a new standardized patient assessment data element under the SDOH category. This Living Situation assessment item is currently collected in the AHC HRSN Screening Tool[47] [48] and was adapted from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) tool.[49] The proposed Living Situation item asks, ''What is your living situation today?'' The proposed response options are: (1) I have a steady place to live; (2) I have a place to live today, but I am worried about losing it in the future; (3) I do not have a steady place to live; (4) Patient unable to respond; and (5) Patient declines to respond. A draft of the proposed Living Situation item can be found in the Downloads section of the HH QRP Quality Measures web page at *https://*

[34] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

[35] Centers for Medicare & Medicaid Services, FY2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49194).

[36] Centers for Medicare & Medicaid Services, FY 2024 Inpatient Psychiatric Prospective Payment System—Rate Update (88 FR 51107 through 51121).

[37] *https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[38] Healthy People 2030 is a long-term, evidence-based effort led by the U.S. Department of Health and Human Services (HHS) that aims to identify nationwide health improvement priorities and improve the health of all Americans.

[39] Kushel, M. B., Gupta, R., Gee, L., & Haas, J.S. (2006). Housing instability and food insecurity as barriers to health care among low-income Americans. *Journal of General Internal Medicine, 21*(1), 71–77. doi: 10.1111/j.1525–1497.2005.00278.x

[40] Homelessness is defined as ''lacking a regular nighttime residence or having a primary nighttime residence that is a temporary shelter or other place not designed for sleeping.'' Crowley, S. (2003). The affordable housing crisis: Residential mobility of poor families and school mobility of poor children. Journal of Negro Education, 72(1), 22–38. doi: 10.2307/3211288.

[41] The 2023 Annual Homeless Assessment Report (AHAR) to Congress. The U.S. Department of Housing and Urban Development 2023. *https://www.huduser.gov/portal/sites/default/files/pdf/2023-AHAR-Part-1.pdf.*

[42] Richards J, & Kuhn R. Unsheltered homelessness and health: A Literature Review. AJPM focus 2023; 2(1):100043. American Journal of Preventive Medicine. Unsheltered Homelessness and Health: A Literature Review (*sciencedirectassets.com*). Accessed 3/1/2024.

[43] Bhat, Aarti C., David M. Almeida, Andrew Fenelon, and Alexis R. Santos-Lozada. ''A longitudinal analysis of the relationship between housing insecurity and physical health among midlife and aging adults in the United States.'' SSM-Population Health 18 (2022): 101128.

[44] Popkin SJ, Hermans A, Oneto AD, Farrell L, Connery M, & Cannington A. 2022. People with Disabilities Living in the US Face Urgent Barriers to Housing: Federal Programs are not Meeting the Housing Needs of Disabled People. Urban Institute. People with Disabilities Living in the US Face Urgent Barriers to Housing_0.pdf (*urban.org*). Accessed 5/29/2024.

[45] U.S. Department of Health & Human Services (HHS), Call to Action, ''Addressing Health Related Social Needs in Communities Across the Nation.'' November 2023. *https://aspe.hhs.gov/sites/default/files/documents/3e2f6140d0087435cc6832bf8cf32618/hhs-call-to-action-health-related-social-needs.pdf.*

[46] Henderson, K.A., Manian, N., Rog, D.J., Robison, E., Jorge, E., AlAbdulmunem, M. ''Addressing Homelessness Among Older Adults'' (Final Report). Washington, DC: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. October 26, 2023.

[47] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf.*

[48] The AHC HRSN Screening Tool Living Situation item includes two questions. In an effort to limit HHA burden, we are only proposing the first question.

[49] National Association of Community Health Centers and Partners, National Association of Community Health Centers, Association of Asian Pacific Community Health Organizations, Association OPC, Institute for Alternative Futures. ''PRAPARE.'' 2017. *https://prapare.org/the-prapare-screening-tool/.*

www.cms.gov/medicare/quality/home-health/home-health-quality-measures.

b. Food

The U.S. Department of Agriculture (USDA), Economic Research Service defines a lack of food security as a household-level economic and social condition of limited or uncertain access to adequate food.[50] Adults who are food insecure may be at an increased risk for a variety of negative health outcomes and health disparities. For example, a study found that food-insecure adults may be at an increased risk for obesity.[51] Nutrition security is also an important component that builds on and complements long standing efforts to advance food security. The USDA defines nutrition security as ''consistent and equitable access to healthy, safe, affordable foods essential to optimal health and well-being.'' [52] While having enough food is one of many predictors for health outcomes, a diet low in nutritious foods is also a factor.[53] Studies have shown that older adults struggling with food security consume fewer calories and nutrients and have lower overall dietary quality than those who are food secure, which can put them at nutritional risk. Older adults are also at a higher risk of developing malnutrition, which is considered a state of deficit, excess, or imbalance in protein, energy, or other nutrients that adversely impacts an individual's own body form, function, and clinical outcomes. About 50% of older adults are affected by malnutrition, which is further aggravated by a lack of food security and poverty.[54] We believe that adopting items to collect and analyze information about a patient's food security at home could provide additional insight into their health complexity and help facilitate coordination with other healthcare providers, facilities, and agencies during transitions of care, so that referrals to address a patient's food security are not lost during vulnerable transition periods. For example, an HHA's registered nurse (RN) or other clinically qualified nutrition professional could work with the patient to plan healthy, affordable food choices prior to discharge.[55] HHAs could also refer any patient that indicates lack of food security to government initiatives such as home delivered meals programs provided by Area Agencies on Aging,[56] the Supplemental Nutrition Assistance Program (SNAP), and food pharmacies (programs to increase access to healthful foods by making them affordable), initiatives that have been associated with lower health care costs and reduced hospitalization and emergency department visits.[57]

We are proposing to adopt two new food-related standardized patient assessment data elements under the SDOH category. These proposed items are based on the Food data elements currently collected in the AHC Screening Tool and were adapted from the U.S. Department of Agriculture 18-item Household Food Security Survey (HFSS).[58] The first proposed Food item states, ''Within the past 12 months, you worried that your food would run out before you got money to buy more.'' The second proposed Food item states, ''Within the past 12 months, the food you bought just didn't last and you didn't have money to get more.'' We propose the same response options for both items: (1) Often true; (2) Sometimes true; (3) Never True; (4) Patient declines to respond; and (5) Patient unable to respond. A draft of the proposed Food items to be adopted as standardized patient assessment data elements under the SDOH category can be found in the Downloads section of the HH QRP Quality Measures web page at *https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures.*

c. Utilities

A lack of energy (utility) security can be defined as an inability to adequately meet basic household energy needs.[59] According to the Department of Energy, one in three households in the U.S. are unable to adequately meet basic household energy needs.[60] The median energy burden for rural households of older adults is considerably higher than that for households without older adults.[61] The consequences associated with a lack of utility security are represented by three primary dimensions: economic, physical, and behavioral. Patients with low incomes are disproportionately affected by high energy costs, and they may be forced to prioritize paying for housing and food over utilities. Among older adults, food insecurity and high energy costs together are prevalent.[62] Some patients with low incomes may face limited housing options and be at increased risk of living in lower-quality physical conditions with malfunctioning heating and cooling systems, poor lighting, and outdated plumbing and electrical systems. Finally, patients with a lack of utility security may use concerning behavioral approaches to cope, such as using stoves and space heaters for heat.[63] In addition, data from the Department of Energy's U.S. Energy Information Administration confirm that a lack of energy security disproportionately affects certain populations, such as low-income and African American households.[64] The effects of a lack of utility security include vulnerability to environmental exposures such as dampness, mold, and thermal discomfort in the home, which

[50] U.S. Department of Agriculture, Economic Research Service (n.d.). *Definitions of food security.* Retrieved March 10, 2022, from *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/definitions-of-food-security/.*

[51] Hernandez, D. C., Reesor, L. M., & Murillo, R. (2017). Food insecurity and adult overweight/obesity: Gender and race/ethnic disparities. *Appetite, 117,* 373–378.

[52] Food and Nutrition Security (n.d.). USDA. *https://www.usda.gov/nutrition-security.*

[53] National Center for Health Statistics. (2022, September 6). Exercise or Physical Activity. Retrieved from Centers for Disease Control and Prevention: *https://www.cdc.gov/nchs/fastats/exercise.htm.*

[54] Food Research & Action Center (FRAC). ''Hunger is a Health Issue for Older Adults: Food Security, Health, and the Federal Nutrition Programs.'' December 2019. *https://frac.org/wp-content/uploads/hunger-is-a-health-issue-for-older-adults-1.pdf.*

[55] Schroeder K, Smaldone A. Food Insecurity: A Concept Analysis. Nurse Forum. 2015 Oct-Dec;50(4):274–84. doi: 10.1111/nuf.12118. Epub 2015 Jan 21. PMID: 25612146; PMCID: PMC4510041.

[56] Administration for Community Living. *Nutrition Services.* Last updated 02/02/2024. Accessed 04/19/2024. *https://acl.gov/programs/health-wellness/nutrition-services.*

[57] Tsega M, Lewis C, McCarthy D, Shah T, Coutts K. Review of Evidence for Health-Related Social Needs Interventions. July 2019. The Commonwealth Fund. *https://www.commwealthfund.org/sites/default/files/2019-07/ROI-EVIDENCE-REVIEW-FINAL-VERSION.pdf.*

[58] More information about the HFSS tool can be found at *https://www.ers.usda.gov/topics/food-nutrition-assistance/food-security-in-the-u-s/survey-tools/.*

[59] Hernández D. Understanding 'energy insecurity' and why it matters to health. Soc Sci Med. 2016 Oct; 167:1–10. doi: 10.1016/j.socscimed.2016.08.029. Epub 2016 Aug 21. PMID: 27592003; PMCID: PMC5114037.

[60] U.S. Energy Information Administration. ''One in Three U.S. Households Faced Challenges in Paying Energy Bills in 2015.'' 2017 Oct 13. *https://www.eia.gov/consumption/residential/reports/2015/energybills/.*

[61] Simes, Miranda, Farzana Khan, and Diana Hernández. ''Energy Insecurity and Social Determinants of Health.'' In Handbook of Social Sciences and Global Public Health, pp. 2119–2137. Cham: Springer International Publishing, 2023.

[62] Simes, Miranda, Farzana Khan, and Diana Hernández. ''Energy Insecurity and Social Determinants of Health.'' In Handbook of Social Sciences and Global Public Health, pp. 2119–2137. Cham: Springer International Publishing, 2023.

[63] Hernández D. ''What 'Merle' Taught Me About Energy Insecurity and Health.'' Health Affairs, VOL.37, NO.3: Advancing Health Equity Narrative Matters. March 2018. *https://doi.org/10.1377/hlthaff.2017.1413.*

[64] U.S. Energy Information Administration. ''One in Three U.S. Households Faced Challenges in Paying Energy Bills in 2015.'' 2017 Oct 13. *https://www.eia.gov/consumption/residential/reports/2015/energybills/.*

have direct effect on patients' health.[65] For example, research has shown associations between a lack of energy security and respiratory conditions as well as mental health–related disparities and poor sleep quality in vulnerable populations such as the elderly, children, the socioeconomically disadvantaged, and the medically vulnerable.[66] We believe adopting an item to collect information about a patient's utility security upon start or resumption of care in HHAs would facilitate the identification of patients who may not have utility security and who may benefit from engagement efforts. For example, HHAs could use the information on utility security to help connect identified patients in need, such as older adults, to programs that can help pay for home energy (heating/cooling) costs, like the Low-Income Home Energy Assistance Program (LIHEAP) [67] or receive broadband internet service through the Affordable Connectivity Program.[68] HHAs can also partner with community care hubs and community-based organizations to assist patients in applying for these and other local utility assistance programs, as well as helping them navigate the enrollment process.[69]

We are proposing to adopt a new item, Utilities, as a new standardized patient assessment data element under the SDOH category. This proposed item is based on the Utilities item currently collected in the AHC HRSN Screening Tool and was adapted from the Children's Sentinel Nutrition Assessment Program (C–SNAP) survey.[70] The proposed Utilities item asks, ''In the past 12 months, has the electric, gas, oil, or water company threatened to shut off services in your home?'' The proposed response options are: (1) Yes; (2) No; (3) Already shut off; (4) Patient unable to respond; and (5) Patient declines to respond. A draft of the proposed Utilities item to be adopted as a standardized patient assessment data element under the SDOH category can be found in the downloads section of the HH QRP Quality Measures web page at *https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures.*

4. Stakeholder Input

We developed our proposal after considering the feedback we received when we proposed the creation of the SDOH category of standardized patient assessment data elements in the CY 2020 HH PPS proposed rule (84 FR 34677 through 34684). Commenters were generally in favor of the concept of collecting SDOH data elements and stated that if implemented appropriately the data could be useful in identifying and addressing health care disparities, as well as refining the risk adjustment of outcome measures. We incorporated this input into the development of this proposal.

We invite comment on the proposal to adopt four new items as standardized patient assessment data elements under the SDOH category beginning with the CY 2027 HH QRP: one living situation item; two food items; and one utilities item.

5. Proposal To Modify the Transportation Item Beginning With the CY 2027 HH QRP Program Year

Beginning January 1, 2023, HHAs began collecting seven standardized patient assessment data elements under the SDOH category on the OASIS Version E. One of these items, A1250. Transportation collects data on whether a lack of transportation has kept a patient from getting to and from medical appointments, meetings, work, or from getting things they need for daily living. This item was adopted as a standardized patient assessment data element under the SDOH category in the CY 2020 HH PPS final rule (84 FR 60478). As we discussed in the CY 2020 HH PPS final rule, we continue to believe that access to transportation for ongoing health care and medication access needs, particularly for those with chronic diseases, is essential to successful chronic disease management and the collection of a Transportation item would facilitate the connection to programs that can address identified needs.

As part of our routine item and measure monitoring work, we continue to assess the implementation of the new SDOH items. We have identified an opportunity to improve the data collection for A1250. Transportation by aligning it with the Transportation category collected in our other programs. Specifically, we are proposing to modify the current Transportation item so that it aligns with a Transportation item collected on the AHC HRSN Screening Tool available to the IPFQR and IQR Programs. A1250. Transportation currently collected in the OASIS asks, ''Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?'' The response options are: (A) Yes, it has kept me from medical appointments or from getting any medications; (B) Yes, it has kept me from non-medical meetings, appointments, work, or from getting things that I need; (C) No; (X) Patient unable to respond; and (Y) Patient declines to respond. The Transportation item collected in the AHC HRSN Screening Tool asks, ''In the past 12 months, has lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?'' The two response options are: (1) Yes; and (2) No. Consistent with the AHC HRSN Screening Tool, we are proposing to modify the A1250. Transportation item currently collected in the OASIS in two ways: (1) revise the look-back period for when the patient experienced lack of reliable transportation; and (2) simplify the response options.

While the current Transportation assessment item uses a look-back period of six to 12 months, we believe the distinction of a 12-month lookback period will reduce ambiguity for both patients and clinicians, and therefore improve the validity of the data collected. Second, we are proposing to simplify the response options. Currently, HHAs separately collect information on whether a lack of reliable transportation has kept the patient from medical appointments or from getting medications, and whether a lack of transportation has kept the patient from non-medical meetings, appointments, work, or from getting things they need. Although transportation barriers can directly affect a person's ability to attend medical appointments and obtain medications, a lack of transportation can also affect a person's health in other

[65] Shahrestanaki, S.K., Rafii, F., Najafi Ghezeljeh, T. *et al.* Patient safety in home health care: a grounded theory study. *BMC Health Serv Res* 23, 467 (2023). *https://doi.org/10.1186/s12913-023-09458-9.*

[66] Siegel, Eva Laura, Kathryn Lane, Ariel Yuan, Lauren A. Smalls-Mantey, Jennifer Laird, Carolyn Olson, and Diana Hernández. ''Energy Insecurity Indicators Associated With Increased Odds Of Respiratory, Mental Health, And Cardiovascular Conditions: Study examines energy insecurity and health conditions.'' Health Affairs 43, no. 2 (2024): 260–268.

[67] Low Income Home Energy Assistance Program (LIHEAP) | The Administration for Children and Families (*hhs.gov*) (*https://www.acf.hhs.gov/ocs/programs/liheap*).

[68] *https://www.fcc.gov/broadbandbenefit.*

[69] National Council on Aging (NCOA). ''How to Make It Easier for Older Adults to Get Energy and Utility Assistance.'' Promising Practices Clearinghouse for Professionals. Jan 13, 2022. *https://www.ncoa.org/article/how-to-make-it-easier-for-older-adults-to-get-energy-and-utility-assistance.*

[70] This validated survey was developed as a clinical indicator of household energy security among pediatric caregivers. Cook, J.T., D.A. Frank., P.H. Casey, R. Rose-Jacobs, M.M. Black, M. Chilton, S. Ettinger de Cuba, et al. ''A Brief Indicator of Household Energy Security: Associations with Food Security, Child Health, and Child Development in US Infants and Toddlers.'' Pediatrics, vol. 122, no. 4, 2008, pp. e874–e875. *https://doi.org/10.1542/peds.2008-0286.*

ways, including accessing goods and services, obtaining adequate food and clothing, and social activities.[71] The proposed modified Transportation item would collect information on whether a lack of reliable transportation has kept the patient from medical appointments, meetings, work *or* from getting things needed for daily living, rather than collecting the information separately. As discussed previously, we believe reliable transportation services are fundamental to a person's overall health, and as a result, the burden of collecting this information separately outweighs its potential benefit.

For the reasons stated, we are proposing to modify A1250. Transportation based on the Transportation item adopted for use in the AHC HRSN Screening Tool and adapted from the PRAPARE tool. The proposed Transportation item asks, ''In the past 12 months, has a lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?'' The proposed response options are: (0) Yes; (1) No; (7) Patient declines to respond; and (8) Patient unable to respond. A draft of the proposed Transportation item to be adopted as a standardized patient assessment data element under the SDOH category can be found on the HH QRP Quality Measures web page at *https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures/downloads.*

We invite comment on this proposal to modify the current Transportation item previously adopted as a standardized patient assessment data element under the SDOH category beginning January 1, 2027, with the CY 2027 HH QRP.

E. Proposal To Update OASIS All-Payer Data Collection

In the CY 2023 HH PPS final rule CMS finalized the end of the temporary suspension of OASIS data collection on non-Medicare/non-Medicaid HHA patients and the requirement for HHAs to submit all-payer OASIS data for purposes of the HH QRP, beginning with the CY 2027 Program Year (87 FR 66862 through 66865). Consistent with the two-quarter phase-in that we typically use when changing data submission items or requirements, HHAs will have an opportunity to begin submitting this data for patients discharged between January 1, 2025, through June 30, 2025, but we will not use that phase-in data to make a compliance determination. We noted that the new all-payer OASIS data reporting will be required beginning with the CY 2027 program year, with data for that program year required for patients discharged between July 1, 2025, and June 30, 2026. For HHAs to operationalize this requirement, CMS determined that further details would be needed to clarify OASIS data collection and submission for non-Medicare/non-Medicaid patients. The CY23 final rule referenced discharge as the time point to identify when all-payer data collection would start but did not address the other data collection time points.

To clarify expectations around the start of OASIS all-payer data collection we are proposing to establish a change from data collection beginning with the OASIS discharge time point to using the start of care (SOC) time point. The SOC is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory period. We will use the M0090 Date Assessment Completed date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments in the phase-in and mandatory periods.

Using the SOC time point ensures agency demographics (for example, Agency's CMS Certification Number (CCN), State and Branch ID#s) and patient demographics (for example, patient name, State, zip code, Social Security number (SSN), gender, date of birth (DOB), payment source) are collected for each non-Medicare/non-Medicaid patient assessment at the start of all-payer OASIS data collection. After these are collected and submitted with the SOC assessment, they are resubmitted with each subsequent OASIS submission (that is, ROC, recert, other follow up, transfer, discharge, death at home). Using the SOC time point would ensure that baseline data is available for use in calculating or risk-adjusting quality measures, and in linking to prior OASIS assessments. The data would also be available for matching purposes to support use of the current quality assessments only (QAO) metric used in the annual payment update (APU) calculation.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173; December 8, 2003) finalized the temporary suspension of OASIS requirements for collection of data on non-Medicare/non-Medicaid patients.[72] The CY 2023 HH PPS final rule ends this temporary suspension of OASIS data collection for non-Medicare/non-Medicaid patients.

CMS is providing a voluntary phase-in period for HHAs to begin OASIS data collection and submission for all non-Medicare/non-Medicaid patients.

- Prior to January 1, 2025—Per the HH CoPs and OASIS guidance, HHAs are required to collect and submit OASIS assessments for all skilled Medicare and/or Medicaid patients, with some exemptions. OASIS assessment time points include start of care, resumption of care, recertification, other follow-up, transfer, discharge, and death at home. The criteria for patients exempt from OASIS data collection are not changing and will continue to include patients under 18, patients receiving maternity services, and patients receiving only personal care, housekeeping or chore services.

- January 1, 2025, through June 30, 2025—For non-Medicare/non-Medicaid patients who are not exempt from OASIS data collection, and who begin receiving home health care services with an OASIS SOC M0090 date from January 1, 2025, through June 30, 2025, OASIS data collection and submission are voluntary. When OASIS data collection and submission are started for a non-Medicare/non-Medicaid patient with the SOC OASIS assessment, HHAs may but are not required to complete all subsequent OASIS time point assessments related to the patient's home health stay (that is, resumption of care, recertification, other follow up, transfer, discharge, and death at home) including assessments completed on or after July 1, 2025.

- Beginning July 1, 2025—For patients with any pay source who are not exempt from OASIS data collection, and who begin receiving home health care services with an OASIS SOC M0090 date on or after July 1, 2025, OASIS data collection and submission to the internet Quality Improvement Evaluation System (iQIES) are required. This includes the SOC OASIS as well as any subsequent OASIS time point assessments relevant to the patient's home health stay (that is, resumption of care, recertification, other follow up, transfer, discharge, and death at home).

We invite comment on this proposal to update requirements for OASIS all-payer data collection beginning January 1, 2025.

[71] Victoria Transport Policy Institute (2016, August 25). Basic access and basic mobility: Meeting society's most important transportation needs. Retrieved from *http://www.vtpi.org/tdm/tdm103.htm.*

[72] E:\PUBLAW\PUBL173.108 (*congress.gov*).

F. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Background

We refer readers to the regulatory text at § 484.45 for information regarding the current policies for reporting HH QRP data.

2. Proposed Reporting Schedule for the Submission of SDOH Assessment Items Beginning January 1, 2027, With the CY 2027 HH QRP

As discussed in section III.D.3. of this proposed rule, we are proposing to adopt four new items as standardized patient assessment data elements in the SDOH category: one living situation item, two food items, and one utilities item, and to modify the transportation item in section III.D.5. of this proposed rule beginning January 1, 2027, with the CY 2027 HH QRP.

We are proposing that HHAs would be required to report these new assessment items using the OASIS beginning with patients admitted on January 1, 2027, for purposes of the CY 2027 HH QRP program year. Starting in CY 2027, HHAs would be required to submit data for the entire calendar year, corresponding to the CY 2028 HH QRP program year with respect to OASIS submission requirements.

We are also proposing that HHAs that submit the living situation, food, utilities, and transportation items with respect to start or resumption of care would be deemed to have submitted those assessment items with respect to both start or resumption of care and discharge, because it is unlikely that the assessment of those items at start or resumption of care will differ from the assessment of the same item at discharge. A draft of the proposed assessment items is available in the Downloads section of the HH QRP Quality Measures web page at *https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures.* As we noted in section III.D.5 of this proposed rule, we continue to assess the implementation of the new items in the SDOH category, including A1250. Transportation, as part of our routine assessment item and measure monitoring work. We analyzed the data home health agencies reported from January 1, 2023, through September 30, 2023 (Q1 2023–Q3 2023) and found that home health patient responses do not significantly change from admission to discharge. Specifically, the proportion of patients who responded ''Yes'' to the A1250 transportation item at start of care or resumption of care (8.87 percent) versus at discharge to community (5.71 percent) differed by only 3.16 percentage points during this period. We find these results convincing, and therefore are proposing to require HHAs to submit the proposed item, transportation, at the start and resumption of care only.

We invite public comment on our proposal to collect data on the following items in the SDOH category start or resumption of care beginning January 1, 2027 with the CY 2027 HH QRP program year: one Living Situation item as described in section III.D.3.a of this proposed rule; two Food items, as described in section III.D.3.b of this proposed rule; one Utilities item as described in section III.D.3.c of this proposed rule; and one Transportation item as described in section III.D.5 of this proposed rule.

G. HH QRP Quality Measure Concepts Under Consideration for Future Years—Request for Information (RFI)

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the following concepts under consideration for future years in the HH QRP: vaccinations, depression, pain management, and substance use disorders. In the CY 2024 HH PPS proposed rule (88FR 43738 through 43740), we published a request for information (RFI) on a set of principles for selecting and prioritizing HH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. Within this proposed rule, we also sought input on data available to develop measures, approaches for data collection, perceived challenges or barriers, and approaches for addressing identified challenges. We refer readers to the CY 2024 HH PPS final rule (88 FR 77772 through 77774) for a summary of the public comments we received in response to the RFI.

Subsequently, our measure development contractor convened a TEP on December 15, 2023 to obtain input on the future measure concepts that could fill the measurement gaps identified in our CY 2024 RFI.[73] The TEP discussed the alignment of PAC and Hospice measures with CMS' ''Universal Foundation'' of quality measures.[74] The Universal Foundation aims to focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for comparisons across programs, and help identify measurement gaps.

In consideration of the feedback, we received from interested parties through these activities, we are seeking input on four concepts for the HH QRP. One is a composite of vaccinations,[75] which could represent overall immunization status of patients such as the Adult Immunization Status measure[76] in the Universal Foundation. A second concept on which we are seeking feedback is the concept of depression for the HH QRP, similar to the Clinical Screening for Depression and Follow-up measure[77] in the Universal Foundation. Third, we are seeking feedback on the concept of pain management. Finally, we seek input on a measure concept relating to substance use disorders, such as the Initiation and Engagement of Substance Use Disorder Treatment measure[78] included in the Universal Foundation of Quality Measures.

While we will not be responding to specific comments in response to this RFI in the CY 2025 HH PPS final rule, we invite public comment on these four measure concepts and intend to use this input to inform our future measure development efforts.

IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing (HHVBP) Model (''original Model'') in nine states on January 1, 2016. The design of the original HHVBP Model leveraged the successes and lessons learned from other CMS value-based purchasing programs and demonstrations to shift from volume-based payments to a model designed to

[73] The Post-Acute Care (PAC) and Hospice Quality Reporting Program Cross-Setting TEP summary report will be published in early summer or as soon as technically feasible. IRFs can monitor the Partnership for Quality Measurement website at *https://mmshub.cms.gov/get-involved/technical-expert-panel/updates for updates.*

[74] Centers for Medicare & Medicaid Services. Aligning Quality Measures Across CMS—the Universal Foundation. November 17, 2023. *https://www.cms.gov/aligning-quality-measures-across-cms-universal-foundation.*

[75] A composite measure can summarize multiple measures through the use of one value or piece of information. More information can be found at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/mms/downloads/composite-measures.pdf.*

[76] CMS Measures Inventory Tool. Adult immunization status measure found at *https://cmit.cms.gov/cmit/#/FamilyView?familyId=26.*

[77] Preventative Care and Screening: Screening for Depression and Follow Up measure found at *https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2023_Measure_134_MIPSCQM.pdf.*

[78] Initiation and Engagement of Substance Use Disorder Treatment measure found at *https://ecqi.healthit.gov/ecqm/ec/2023/cms0137v11.*

promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original HHVBP Model were to—

- Provide higher incentives for better quality care with greater efficiency;
- Study new potential quality and efficiency measures for appropriateness in the home health setting; and
- Enhance the current public reporting process.

The original HHVBP Model resulted in an average 4.6 percent improvement in HHAs' total performance scores (TPS) and an average annual savings of $141 million to Medicare without evidence of adverse risks.[79] The evaluation of the original Model also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) stays, resulting in reductions in inpatient and SNF spending. The U.S. Secretary of Health and Human Services determined that expansion of the original HHVBP Model would further reduce Medicare spending and improve the quality of care. In October 2020, the CMS Chief Actuary certified that expansion of the HHVBP Model would produce Medicare savings if expanded to all States.[80]

On January 8, 2021, CMS announced the certification of the HHVBP Model for expansion nationwide, as well as the intent to expand the Model through notice and comment rulemaking.[81]

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) we finalized the decision to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. The first payment year is CY 2025 based on the first performance year which was CY 2023. Our codified policies for the expanded HHVBP Model can be found in our regulations at 42 CFR part 484, subpart F, §§ 484.300 through 484.375.

B. Request for Information on Future Performance Measure Concepts for the Expanded HHVBP Model

The expanded HHVBP Model provides an opportunity to examine a broad array of quality measures that address critical gaps in care. A comprehensive review of the Value-Based Purchasing (VBP) experience, conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), identified several objectives for HHVBP measures.[82] The recommended objectives emphasize measuring patient outcomes and functional status; appropriateness of care; and incentives for providers to build infrastructure to facilitate measurement within the quality framework. The study identified the following seven objectives which served as guiding principles for the development of performance measures used in the original HHVBP Model:

- Use a broad measure set that captures the complexity of the HHA service provided.
- Incorporate the flexibility to include Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 measures that are cross-cutting amongst post-acute care settings.
- Develop second-generation measures of patient outcomes, health and functional status, shared decision making, and patient activation.
- Include a balance of process, outcome, and patient experience measures.
- Advance the ability to measure cost and value.
- Add measures for appropriateness or overuse.
- Promote infrastructure investments.

A central driver of the process used to select measures for the original HHVBP Model was incorporating innovative thinking from the field while simultaneously drawing on evidence-based literature and documented best practices. Broadly, measures were selected based on their impact on care delivery and to support the goal of improving health outcomes, quality, safety, efficiency, and experience of care for patients.

As we continue to leverage our value-based purchasing initiatives to improve the quality of care furnished across healthcare settings, we are interested in considering new performance measures for inclusion in the expanded HHVBP Model. We specifically request public comments on several specific performance measures as well as general comments on other future model concepts that may be considered for inclusion in the expanded HHVBP Model. These measures are based on input from the HHVBP Technical Expert Panel (TEP), which met in Fall 2023. The TEP included experts from the home health setting specializing in quality assurance, patient advocacy, clinical work, and measure development. The meeting included a discussion of potential measures for inclusion in the expanded HHVBP Model. These include a combination of new measure concepts (for example, family caregiver measure), already developed measures that are not currently in the measure set for the expanded HHVBP Model (for example, Medicare Spending per Beneficiary (MSPB)), and new OASIS-based and claims-based measures.

- *Family caregiver measure:* Generally, TEP members were very supportive of future development of a family caregiver measure. One TEP member encouraged CMS to ''think outside the box'' to find ways of including the caregiver's voice in quality reporting. The TEP discussed OASIS items that provide information related to the patient's caregiver status. While acknowledging that the focus of the Medicare home health benefit is the patient, not the caregiver, they recommended that CMS consider the caregiver as a partner and measure caregivers' needs and not just the needs as they relate to the beneficiary. The TEP noted that the caregivers are often the reason patients are even able to be at home (vs. receiving care in the more costly nursing home setting). CMS intends to develop a patient-reported outcome performance measure (PRO–PM) to assess caregiver burden in the Guiding an Improved Dementia Experience (GUIDE) Model that may be a useful example for caregiver measures that may be developed for HHVBP.[83] Creating one or more measures based on an HHA's ability to meet caregiver needs would permit measurement of changes in caregiver quality-of-life.
- *Falls with injury (claims-based):* Several TEP members suggested that CMS explore a claims-based measure of falls with injury. One TEP member noted an Office of Inspector General (OIG) study that found that HHAs failed to report 55 percent of falls leading to major injuries and hospitalizations on their OASIS data.[84] While it may not be possible to identify all falls from claims data, a claims-based measure may be more accurate, although, as with other claims-based measures, data would only be available for Fee for Service patients. Due to the high rate of non-reporting, the OASIS-based falls measure may not

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

[80] *https://www.cms.gov/files/document/certificationhome-health-value-based-purchasing-hhvbpmodel.pdf.*

[81] *https://www.cms.gov/newsroom/press-releases/cms-takes-action-improve-home-health-care-seniors-announces-intent-expand-home-health-value-based.*

[82] U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2014). Measuring Success in Health Care Value-Based Purchasing Programs. Cheryl L. Damberg et al. on behalf of RAND Health.

[83] For more details on the GUIDE Model, see the Model web page (*https://www.cms.gov/priorities/innovation/innovation-models/guide*). For more details on the caregiver measures being developed for GUIDE, see the Request for Applications (*https://www.cms.gov/files/document/guide-rfa.pdf*).

[84] *https://oig.hhs.gov/oei/reports/OEI-05-22-00290.asp.*

provide accurate information about the incidence of these falls.

• *Medicare spending per Beneficiary:* The TEP also discussed potentially adding the MSPB measure to the HHVBP applicable measure set. This cross-setting measure is part of the Home Health Quality Reporting Program and is currently publicly reported on Care Compare. MSPB may be a valid tool for measuring the value of the care that HHAs provide that may be appropriate for use in the expanded HHVBP Model. The measure would provide information on the efficiency of home health providers, as measured by Medicare payments for their patients.

• *Function measures to complement existing cross-setting Discharge (DC) Function measure:* Several TEP members raised a concern that the measure does not include the full self-care/activities of daily living elements (for example, bathing, dressing), which they noted as critically important for home health patients and caregivers. Another TEP member indicated that patients often already have capacity to do things like roll and sit up when they enter home health care but may not be able to bathe or get dressed without assistance. The TEP emphasized the importance of functional cognition, which is included in OASIS item GG0100 as part of prior functional status but is not included as part of the current DC Function measure.

As we continue to explore refinements to the expanded HHVBP Model, we request comments related to adding the potential performance measures described previously to the HHVBP Measure Set. We also request comments about other potential performance measures that we should consider for the expanded HHVBP Model.

C. Future Approaches to Health Equity in the Expanded HHVBP Model

In alignment with the President's Executive orders [85] to support underserved communities, CMS is working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive. As we continue to leverage our value-based purchasing initiatives to improve the quality of care furnished across healthcare settings, we are interested in exploring the role of health equity in creating better health outcomes for all populations in our programs and models. In the CY 2023 HH PPS final rule, we stated that we are committed to achieving equity in health care outcomes for beneficiaries by supporting providers in quality improvement activities to reduce health disparities, enabling beneficiaries to make more informed decisions, and promoting provider accountability for health care disparities.[86]

The CY 2023 HH PPS rule (87 FR 66874 through 66876) included an RFI, ''Future Approaches to Health Equity in the expanded HHVBP Model.'' The RFI requested feedback on policy changes that we should consider on the topic of health equity and specific actions the expanded HHVBP Model should take to address healthcare disparities and advance health equity. We specifically requested comments on whether we should consider incorporating adjustments into the expanded HHVBP Model to reflect the varied patient populations that HHAs serve around the country and tie health equity outcomes to the payment adjustments we make based on HHA performance under the Model. One possible approach is to make adjustments at the measure level such as stratification by which additional points are provided to HHAs that provide care to underserved communities (for example, based on dual status or other metrics).[87] Payment adjustments could also be incorporated at the scoring level in forms such as modified benchmarks, points adjustments, or modified payment adjustment percentages (for example, peer comparison groups based on whether the HHA includes a high proportion of dual eligible beneficiaries). We requested commenters' views on which of these adjustments, if any, would be most effective for the expanded HHVBP Model. Commenters shared that relevant data collection and appropriate stratification are very important in addressing any health equity gaps. While not suggesting specific approaches, these commenters noted that CMS should consider potential stratification of health outcomes. Stakeholders, including providers, also shared their strategies for addressing health disparities, noting that this was an important commitment for many health provider organizations.

Several previous studies have found that historically underserved communities, including Medicare beneficiaries who are dually enrolled in Medicaid, live in a low-income neighborhood, or are Black, receive lower quality home health care relative to communities not historically underserved.[88] Previous studies have found that patients from underserved communities have higher rates of hospital readmissions, are more likely to be discharged without functional improvement,[89] are less likely to receive care from high-quality HHAs, and have worse patient-reported care experiences. Improving the quality of care for these underserved communities is an important quality improvement goal under the expanded HHVBP Model.

Disparities in health care outcomes may result from differences within HHAs (for example, patients from underserved communities within certain HHAs service areas are less likely to have good outcomes, such as functional improvement, discharge to community, and avoiding readmission to a hospital). These disparities may also result from differences across HHAs. That is, patients from underserved communities are less likely than other patients to receive care from good quality HHAs and thus at higher risk of poor outcomes.[90] The literature is mixed on the sources of these disparities. One study found that differences in readmission rates for underserved communities were primarily within, rather than across, HHAs.[91] Another study found that

[85] Executive Orders 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' and 14091, ''Executive Order on Further Advancing Racial Equity and Support for Underserved Communities Through The Federal Government.''

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

[87] CMS defines an ''underserved community'' as ''individuals who share a particular characteristic—demographic, geographic (urban or rural), or other factor—that results in them being systemically denied full opportunity to participate in aspects of economic, social, and civic life. (Source: *https://www.cms.gov/priorities/innovation/key-concepts/health-equity*).

[88] Joynt Maddox, K.E., Chen, L.M., Zuckerman, R., & Epstein, A.M. (2018). Association Between Race, Neighborhood, and Medicaid Enrollment and Outcomes in Medicare Home Health Care. Journal of the American Geriatrics Society, 66(2), 239–246. *https://doi.org/10.1111/jgs.15082.*

[89] Fashaw-Walters, S.A., Rahman, M., Jarrín, O.F., Gee, G., Mor, V., Nkimbeng, M., & Thomas, K.S. (2023). Getting to the root: Examining within and between home health agency inequities in functional improvement. Health Services Research. *https://doi.org/10.1111/1475-6773.14194.*

[90] Fashaw-Walters, S.A., Rahman, M., Gee, G., Mor, V., White, M., & Thomas, K.S. (2022). Out Of Reach: Inequities in the Use of High-Quality Home Health Agencies. Health Affairs (Project Hope), 41(2), 247–255. *https://doi.org/10.1377/hlthaff.2021.01408.*

[91] Joynt Maddox, K.E., Chen, L.M., Zuckerman, R., & Epstein, A.M. (2018). Association Between Race, Neighborhood, and Medicaid Enrollment and Outcomes in Medicare Home Health Care. Journal

Continued

differences both within and across HHAs contribute to the overall disparities in patients' functional improvement.[92] This same study found that roughly half of observed individual-level disparities in the use of high-quality home health agencies was attributable to neighborhood-level factors.[93] Differences in care experience for underserved communities were explained by differences both within and across HHAs, but the within-HHA variations more often accounted for a greater proportion of the differences.[94]

We have been exploring several potential approaches for integrating health equity concepts into the expanded HHVBP Model. Considerations for evaluating these approaches include the following:

- *Effectiveness:* Does the approach further the model test? What would its impact on underserved communities be?
- *Feasibility:* How long would it take to implement the approach? Are the necessary data currently being collected? How many HHAs would be included?
- *Reliability:* Does the approach allow for reliable measurement of health equity within HHAs?
- *Alignment:* Is this approach aligned with other Medicare quality and VBP Programs?

D. Social Risk Factors

As part of our work developing potential equity measures, we are exploring potential definitions to use for defining historically underserved communities. Building on feedback from the CY 2024 SNF VBP proposals, our analyses have focused on three potential social risk factors Dual eligible status (DES), Area Deprivation Index (ADI), and Medicaid as sole payment source that can serve as a proxy to identify the underserved. Note that we also examined low-income subsidy (LIS) as a potential measure of equity but did not include it in further analyses, because the correlation for the Dual Eligible Status (DES) proportion and the LIS eligibility proportion is above 0.98. have not yet examined low-income subsidy (LIS) eligibility. We also plan to assess disparities between rural and urban home health providers and patients when analyzing social risk factors, perhaps measuring rurality using the rural-urban commuting area (RUCA) codes, which classify U.S. census tracts using measures of population density, urbanization, and daily commuting.

E. Approaches to a Potential Health Equity Adjustment for the Expanded HHVBP Model

One of the approaches that we have explored is the Health Equity Adjustment (HEA) that will begin in the Skilled Nursing Facility (SNF) VBP starting with the FY 2027 program year. The HEA is calculated using a methodology that considers a SNF's performance on the SNF VBP quality measures and the proportion of the SNF's residents with DES. Under the HEA, SNFs that perform well on the SNF VBP quality measures and serve a higher proportion of residents with DES will earn HEA bonus points are added to normalized sum of all points a SNF is awarded for each measure. That sum is then the final SNF Performance Score. More information on the HEA can be found in the FY 2024 SNF PPS final rule (88 FR 53304).

We used the HEA methodology that was finalized for the SNF VBP to simulate how that methodology would impact the expanded HHVBP Model, using the current measure set for the Model and July 2023 Interim Performance Report (IPR) data. A limitation of using the July 2023 IPR data for these analyses is that the TPS for the July 2023 IPRs was mainly based on achievement points—there are no improvement points for the claims-based and HHCAHPS measures (due to lags in the data for these measures) and only small improvement points for the OASIS-based measures. This may distort results of the equity implications of the HEA methodology, but we believe that using the more current data is preferable to using earlier data from prior to the public health emergency. We used data on the proportion of HHA patients who are dually eligible at any point during the performance year. The HEA methodology is fully described in the FY 2024 Skilled Nursing Facility Prospective Payment System final rule (88 FR 53307 through 53316) that included—

- Determine number of measures for which HHA is a top tier performer;
- Calculate measure performance scaler;
- Calculate underserved multiplier;
- Calculate HEA Bonus Points; and
- Add HEA Bonus Points to the Normalized Sum of all Points Awarded for Each Measure.

Using the original TPS and a TPS measure that includes the HEA bonus points), we simulated payment adjustment amounts with and without the HEA. We examined the change in payment adjustment percentage for HHAs based on their dual eligibility status (for example, decile in terms of percentage of dual eligible patients) and HEA bonus points.

Of the 10,218 active HHAs in the July 2023 quarterly monitoring analytic file, 9,591 (93.9 percent) have information on the number of beneficiaries with dual eligible status (DES) that were served by the HHA in the performance year. Of these HHAs, a TPS was calculated for 7,556. Because the HEA operates by adding points to the TPS, it is only possible to calculate a TPS including the HEA for these 7,556 HHAs that had a valid TPS.

We found that the average TPS was higher for HHAs in the highest decile in terms of share of beneficiaries with DES than for HHAs in any other decile, before applying the HEA. Applying the HEA primarily increased TPS for these HHAs that were already high performing, which increased the gap in the average payment adjustment for these HHAs and the average payment adjustment for HHAs serving a lower share of beneficiaries with DES. As a result, we concluded that the HEA using DES as the proxy for the underserved, as designed for SNF VBP, may not the best approach for the home health setting. In contrast, the average TPS was higher for HHAs with a relatively low share of beneficiaries living in a neighborhood with a high ADI.

We also plan to consider how changes to the definition of the underserved population, as codified in the SNF VBP reg text at § 413.338(a) would alter the effects of the HEA. In contrast to the results for dual eligibility, we have found that average TPS was lower for HHAs serving a high share of beneficiaries living in a neighborhood with a high ADI. We also found that HHAs in the highest ADI quintile and highest DES quintile had lower average TPS than other groups. These results suggest that defining the underserved population using ADI or a combination of ADI and DES would alter the effects of the HEA. We are also examining measures of the underserved population that are based on the percentage of

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of the American Geriatrics Society, 66(2), 239–246. *https://doi.org/10.1111/jgs.15082.*

[92] Fashaw-Walters, S.A., Rahman, M., Jarrín, O.F., Gee, G., Mor, V., Nkimbeng, M., & Thomas, K.S. (2023). Getting to the root: Examining within and between home health agency inequities in functional improvement. Health Services Research. *https://doi.org/10.1111/1475-6773.14194.*

[93] Fashaw-Walters SA, Rahman M, Gee G, Mor V, White M, Thomas KS. Out Of Reach: Inequities In The Use Of High-Quality Home Health Agencies. Health Aff (Millwood). 2022 Feb;41(2):247–255. doi: 10.1377/hlthaff.2021.01408. PMID: 35130066; PMCID: PMC8883595.

[94] Joynt Maddox, K.E., Chen, L.M., Zuckerman, R. and Epstein, A.M. (2018), Association Between Race, Neighborhood, and Medicaid Enrollment and Outcomes in Medicare Home Health Care. J Am Geriatr Soc, 66: 239–246. *https://doi.org/10.1111/jgs.15082.*

patients with Medicaid as the only payment source.

F. Other Health Equity Measures

We are also exploring other health equity measures that would more directly focus on certain disparities. These could be structured in several different ways:

- Measure(s) for particular underserved communities: Performance on one or more measures for specific underserved communities (for example, based on DES).
- Measure(s) based on within-provider differences in performance for underserved communities (for example, based on DES): This type of measure could be based on a single outcome or multiple outcomes (that is, a composite measure).
- Measure(s) based on the worst performing group: Calculate performance scores for multiple patient groups and set the measure performance equal to the score for the worst performing group.

We have examined the reportability of these other health equity measures and have found that several HHAs will not have a sufficient number of DES beneficiaries for these measures to be calculated. Our analyses of data used for the July 2023 IPRs found that, overall, 25.4 percent of HHAs served fewer than 12 beneficiaries with DES. This suggests that roughly one-fourth of HHAs may not serve enough beneficiaries with DES to calculate a performance measure using only beneficiaries with DES. The percentage of HHAs that served fewer than 12 beneficiaries with DES or fewer than 12 beneficiaries without DES was 36.5 percent. Although the reportability for these measures do exclude some smaller HHAs that serve fewer underserved patients, the reportability level will be closely aligned to the current SNF VBP HEA. As the 25.4 percent proportion that are not reported is not that much more than is currently being excluded on the SNF VBP HEA where SNFs in the bottom 20 percent of proportion duals are excluded. The impact or reportability of a potential HHVBP HEA needs more analysis for future consideration.

Looking forward, we recognize that the exact structure of the current SNF VBP HEA may not be the most efficient approach for the unique attributes of care being provided in the home versus care in the SNF. However, CMS is committed to and working towards the establishment of an HHVBP HEA that rewards HHAs that provide high quality care to underserved communities. We will continue to explore the addition of other measures, using other proxies for identifying the underserved and possibly adjusting the scoring mechanism to be more effective at addressing the issue.

As a reminder, we stated in the CY 2024 HH PPS final rule (88 FR 77790), we will gather at least 2 years of performance data, and study effects of the expanded Model on health equity outcomes before incorporating any potential changes to the expanded Model regarding health equity.

V. Medicare Home Intravenous Immune Globulin (IVIG) Items and Services

A. General Background

1. Statutory Background

Division FF, section 4134 of the CAA, 2023 added coverage and payment of items and services related to administration of IVIG in a patient's home of a patient with a diagnosed primary immune deficiency disease furnished on or after January 1, 2024. Division FF, section 4134(a) of the CAA, 2023 amended the existing IVIG benefit category at section 1861(s)(2)(Z) of the Act by adding coverage for IVIG administration items and services in a patient's home of a patient with a diagnosed primary immune deficiency disease. This benefit covers items and services related to administration of IVIG in a patient's home of a patient with a diagnosed primary immune deficiency disease. In addition, section 4134(b) of Division FF of the CAA, 2023 amended section 1842(o) of the Act by adding a new paragraph (8) that established the payment for IVIG administration items and services. Under the CAA, 2023 provision, payment for these IVIG administration items and services is required to be a bundled payment separate from the payment for the IVIG product, made to a supplier for all items and services related to administration of IVIG furnished in the home during a calendar day.

2. Overview

Primary immune deficiency diseases (PIDD) are conditions triggered by genetic defects that cause a lack of and/or impairment in antibody function, resulting in the body's immune system not being able to function in a normal way. Immune globulin (Ig) therapy is used to temporarily replace some of the antibodies (that is, immunoglobulins) that are missing or not functioning properly in people with PIDD.[95] The goal of Ig therapy is to use Ig obtained from normal donor plasma to maintain a sufficient level of antibodies in the blood of individuals with PIDD to fight off bacteria and viruses. Ig is formulated for both intravenous and subcutaneous administration (SCIg). Clinicians can prescribe either product to the beneficiary with PIDD according to clinical need and preference, and beneficiaries can switch between intravenous and subcutaneous administration of Ig.

3. Legislative Summary

Section 642 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pu Law 108–173) amended section 1861 of the Act to provide Medicare Part B coverage of the IVIG product for the treatment of PIDD in the home, but not the items and services involved with administration.

Section 101 of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Medicare IVIG Access Act) (Pub. L. 112–242) mandated the establishment, implementation, and evaluation of a 3-year Medicare Intravenous Immune Globulin (IVIG) Demonstration Project (the Demonstration) under Part B of title XVIII of the Act. The Demonstration was implemented to evaluate the benefits of providing coverage and payment for items and services needed for the home administration of IVIG for the treatment of PIDD, and to determine if it would improve access to home IVIG therapy for patients with PIDD. The Medicare IVIG Access Act mandated that Medicare would establish a per visit payment amount for the items and services necessary for the home administration of IVIG therapy for beneficiaries with specific PIDD diagnoses. The Demonstration did not include Medicare payment for the IVIG product which continues to be paid under Part B in accordance with sections 1842(o) and 1847(A) of the Act. The Demonstration covered and paid a per visit payment amount for the items and services needed for the administration of IVIG in the home. Items may include infusion set and tubing, and services include nursing services to complete an infusion of IVIG lasting on average three to five hours.[96]

On September 28, 2017, Congress passed the Disaster Tax Relief and Airport and Airway Extension Act of 2017 (Pub. L. 115–63). Section 302 of Public Law 115–63 extended the

[95] Perez EE, Orange JS, Bonilla F, et al. (2017) Update on the use of immunoglobulin in human disease: A review of evidence; Journal Allergy Clin Immunol. 139(3S): S1–S46.

[96] Updated Interim Report to Congress: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration Project, 2022: *https://innovation.cms.gov/data-and-reports/2022/ivig-updatedintrtc.*

Demonstration through December 31, 2020.

Division CC, section 104, of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260), further extended the Demonstration for another 3 years through December 31, 2023.

Division FF, section 4134 of the CAA, 2023 (CAA, 2023) (Pub. L. 117–328) mandated that CMS establish permanent coverage and payment for items and services related to administration of IVIG in a patient's home of a patient with PIDD. The permanent home IVIG items and services payment is effective for home IVIG administration furnished on or after January 1, 2024. Payment for these items and services is required to be a separate bundled payment made to a supplier for all administration items and services furnished in the home during a calendar day. The statute provides that payment amount may be based on the amount established under the Demonstration. The standard Part B coinsurance and the Part B deductible is required to apply. In addition, that statute states that the separate bundled payment for these IVIG administration items and services does not apply for individuals receiving services under the Medicare home health benefit. The CAA, 2023 provision clarifies that a supplier who furnishes these services meet the requirements of a supplier of medical equipment and supplies.

4. Demonstration Overview

Under the Demonstration, Medicare provided a bundled payment under Part B, that is separate from the IVIG product, for items and services that are necessary to administer IVIG in the home to enrolled beneficiaries who are not otherwise homebound and receiving services under the home health benefit. The Demonstration only applied to situations where the beneficiary required IVIG for the treatment of certain PIDD diagnoses or was receiving SCIg to treat PIDD and wished to switch to IVIG.

Services covered under the Demonstration were required to be provided and billed by specialty pharmacies, enrolled as durable medical equipment (DME) suppliers, that provided the Medicare Part B-covered Ig. The covered items and services under the Demonstration were paid as a single bundle and subject to coinsurance and deductible in the same manner as other Part B services. HHAs were not eligible to bill for services covered under the Demonstration but could bill for services related to the administration of IVIG if the patient was receiving services under a home health episode of care, in which case the home health payment covered the items and services.

In order to participate in the Demonstration, beneficiaries must have met the following requirements:

- Be eligible to have the IVIG paid for at home under Part B FFS.
- Have a diagnosis of PIDD.
- Not be enrolled in a Medicare Advantage plan.
- Cannot be in a home health episode of care on the date of service (in such circumstances, the home health payment covers the services).
- Must receive the service in their home or a setting that is ''home like''.

To participate in the Demonstration, the beneficiary was required to submit an application, signed by their physician.

DME suppliers billing for the items and services covered under the Demonstration must have met the following requirements:

- Meet all Medicare, as well as other national, state, and local standards and regulations applicable to the provision of services related to home infusion of IVIG.
- Be enrolled and current with the National Supplier Clearinghouse.
- Be able to bill the DME Medicare Administrative Contractors (MACs).

CMS implemented a bundled per visit payment amount under the Demonstration, statutorily required to be based on the national per visit low-utilization payment adjustment (LUPA) for skilled nursing services used under the Medicare HH PPS established under section 1895 of the Act. The payment amount was subject to coinsurance and deductible.

For billing under the Demonstration, CMS established a ''Q'' code for services, supplies, and accessories used in the home:

- Q2052—(Long Description)—Services, supplies, and accessories used in the home under Medicare Intravenous immune globulin (IVIG) Demonstration.
- Q2052—(Short Description)—IVIG demo, services/supplies.

Suppliers billed Q2052 as a separate claim line on the same claim for the IVIG product.

B. Scope of Expanded IVIG Benefit

As discussed previously, Division FF, section 4134 of the CAA, 2023, added coverage of items and services related to the administration of IVIG in a patient's home, to the existing IVIG benefit category at section 1861(s)(2)(Z) of the Act, effective January 1, 2024. IVIG is covered in the home under Part B if all the following criteria are met:

- It is an approved pooled plasma derivative for the treatment of primary immune deficiency disease.
- The patient has a diagnosis of primary immune deficiency disease.
- The IVIG is administered in the home.
- The treating practitioner has determined that administration of the IVIG in the patient's home is medically appropriate.

Therefore, as section 4134(a)(1) of the CAA, 2023, adds the items and services (furnished on or after January 1, 2024) related to the administration of IVIG to the benefit category defined under section 1861(s)(2)(Z) of the Act (the Social Security Act provision requiring coverage of the IVIG product in the home), the same beneficiary eligibility requirements for the IVIG product apply for the IVIG administration items and services. Subpart B of part 410 of the regulations set out the medical and other health services requirements under Part B. The regulations at § 410.10 identify the services that are subject to the conditions and limitations specified in this subpart. Section 410.10(y) includes intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases. Section 410.12 outlines general basic conditions and limitations for coverage of medical and other health services under Part B, as identified in § 410.10. Section 410.12(a) includes the conditions that must be met for these services to be covered, and include the following:

- When *the services must be furnished.* The services must be furnished while the individual is in a period of entitlement.
- By *whom the services must be furnished.* The services must be furnished by a facility or other entity as specified in §§ 410.14 through 410.69.
- Physician *certification and recertification requirements.* If the services are subject to physician certification requirements, they must be certified as being medically necessary, and as meeting other applicable requirements, in accordance with subpart B of part 424.

As the definition of IVIG at section 1861(zz) of the Act now includes the items and services necessary to administer IVIG in the home, in the CY 2024 HH PPS final rule (88 FR 77793), we finalized the amendment to the regulation at § 410.10(y) to add ''items and services''. Furthermore, sub-regulatory guidance documents (that is, IVIG LCD (33610) [97] and IVIG Policy

[97] *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33610.*

Article (A52509)[98]) provide direction on coding and coverage for the IVIG product at home. Through the Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610),[99] the Durable Medical Equipment Medicare administrative contractors (DME MACs) specify the Healthcare Common Procedure Coding System (HCPCS) codes for which IVIG derivatives are covered under this benefit. Therefore, a beneficiary must be receiving one of the IVIG derivatives specified under the LCD for IVIG to qualify to receive the items and services covered under section 1861(s)(2)(Z) of the Act. Furthermore, for any item (including IVIG) to be covered by Medicare, it must (1) be eligible for a defined Medicare benefit category, (2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. Policy guidance for the LCD for IVIG[100] identifies the ICD–10–CM codes that support medical necessity for the provision of IVIG in the home. These diagnosis codes are listed in table 40.

TABLE 40: ICD-10-CM CODES THAT SUPPORT MEDICAL NECESSITY FOR HOME IVIG

Code	Description
D80.0	Hereditary hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.82	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G11.3	Cerebellar ataxia with defective DNA repair

In accordance with this guidance, a beneficiary must be diagnosed with one of the primary immune deficiencies identified by the ICD–10–CM codes, set out in table 40 and as updated in subregulatory guidance, to qualify to receive the items and services covered under section 1861(s)(2)(Z) of the Act. This policy guidance is revised as needed by the DME MACs. And finally, to qualify to receive IVIG in the home, section 1861(zz) of the Act requires that a treating practitioner must have determined that administration of the IVIG in the patient's home is medically appropriate. Accordingly, we updated the sub-regulatory guidance pursuant to the CAA, 2023 to reflect the expansion of the benefit to the items and services related to the home administration of IVIG. Leveraging the existing regulations and sub-regulatory guidance maintains one set of standards across the entire IVIG benefit (that is, for the product and for the related items and services needed for home administration).

1. Items and Services Related to the Home Administration of IVIG

Section 101(c) of the Medicare IVIG Access Act established coverage for items and services needed for the in-home administration of IVIG for the treatment of primary immunodeficiencies under a Medicare demonstration program. In the CY 2024 HH PPS final rule, we stated that we interpreted section 4134 of the CAA, 2023 to make permanent coverage of the same items and services under the existing IVIG Demonstration to promote

[98] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52509.*

[99] Local Coverage Determination (LCD): IVIG (L33610) *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33610&ContrId=389.*

[100] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52509.*

continuous and comprehensive coverage for beneficiaries who choose to receive home IVIG therapy (88 FR 77794). Under the Demonstration, the bundled payment for the items and services necessary to administer the drug intravenously in the home included the infusion set and tubing, and nursing services to complete an infusion of IVIG lasting on average three to five hours.[101] Although ''items and services'' are not explicitly defined under section 4134 of the CAA, 2023, we stated in the CY 2024 HH PPS proposed rule (88 FR 43755) that we believed the items and services covered under the Demonstration are inherently the same items and services that would be covered under the payment added to the benefit category at section 1861(s)(2)(Z) of the Act. We also did not enumerate a list of services that must be included in the separate bundled payment; however, we stated that we anticipated the nursing services would include such professional services as IVIG administration, assessment and site care, and education (88 FR 43755). Moreover, we stated that it is up to the provider to determine the services and supplies that are appropriate and necessary to administer the IVIG for each individual, and this may or may not include the use of a pump. Because IVIG does not have to be administered through a pump (although it can be), external infusion pumps are not covered under the DME benefit for the administration of IVIG. An external infusion pump is only covered under the DME benefit if the infusion pump is necessary to safely administer the drug. The Local Coverage Determination (LCD) for External Infusion Pumps identify the drugs and biologicals that the DME Medicare Administrative Contractors (MACs) have determined require the use of such pumps and cannot be administered via a disposable elastomeric pump or the gravity drip method.[102] As such, under the IVIG Demonstration, coverage did not extend to the DME pump, and thereby, is not covered separately under the home IVIG items and services payment.

2. Home IVIG Items and Services and the Relationship to/Interaction With Home Health and Home Infusion Therapy Services

Prior to enactment of the CAA, 2023, IVIG administration items and services were explicitly excluded from coverage under the Part B IVIG benefit. However, if a beneficiary was considered homebound and qualified for the home health benefit, the items and services needed to administer IVIG in the home could be covered as home health services. Section 4134(b) of the CAA, 2023 excludes the IVIG items and services bundled payment in the case of an individual receiving home health services under section 1895 of the Act. Therefore, we clarified in the CY 2024 HH PPS final rule that a beneficiary does not have to be considered confined to the home (that is, homebound) in order to be eligible for the home IVIG benefit; however, homebound beneficiaries requiring items and services related to the administration of home IVIG, and who are receiving services under a home health plan of care, may continue to receive services related to the administration of home IVIG as covered home health services (88 FR 77794). We also clarified that the items and services related to the administration of IVIG in the home, and as identified on the home health plan of care, would be included in the payment for the 30-day home health period payment. HHAs must provide home health items and services included on the plan of care either directly or under arrangement and must bill and be paid under the HH PPS for such covered home health services. If an HHA is unable to furnish the items and services related to the administration of IVIG (as indicated in the plan of care) in the home, they are responsible for arranging these services (including arranging for services in an outpatient facility) and are required to bill these services as home health services under the HH PPS (88 FR 77795).

Regarding the home infusion therapy (HIT) services benefit, we reminded readers that Medicare payment for home infusion therapy services is for services furnished in coordination with the furnishing of intravenous and subcutaneous infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps (L33794),[103] with the exception of insulin pump systems and certain drugs and biologicals on a self-administered drug exclusion list (88 FR 77794). For the drugs and biologicals to be covered under the Part B DME benefit they must require infusion through an external infusion pump. If the drug or biological can be infused through a disposable pump or by a gravity drip, it does not meet this criterion. IVIG does not require an external infusion pump for administration purposes and therefore, is explicitly excluded from the DME LCD for External Infusion Pumps. However, subcutaneous immunoglobulin (SCIg) is covered under the DME LCD for External Infusion Pumps, and items and services for administration of SCIg in the home are covered under the HIT services benefit. While a DME supplier and a HIT supplier (or a DME supplier also enrolled as a HIT supplier) could not furnish services related to the administration of immunoglobulin (either IVIG or SCIg) to the same beneficiary on the same day, a beneficiary could potentially receive services under both benefits for services related to the infusion of different drugs. For example, a DME supplier also accredited and enrolled as a HIT supplier, could furnish HIT services to a beneficiary receiving intravenous acyclovir as well as IVIG, and bill both the IVIG and the HIT services benefits on the same date of service. We also recognize that a beneficiary may, on occasion, switch from receiving immunoglobulin subcutaneously to intravenously and vice versa, and as such, utilize both the HIT services and the IVIG benefits within the same month.

C. Home IVIG Administration Items and Services Payment

Section 101 of the Medicare IVIG Access Act established the authority for a Demonstration providing payment for items and services needed for the in-home administration of IVIG. In the CY 2024 HH PPS final rule, we stated that we believed the provisions established under that law serve as the basis for the conditions for payment with respect to the requirements that must be met for Medicare payment to be made to suppliers for the items and services covered under section 1861(s)(2)(Z) of the Act and clarified that the relevant regulations and subregulatory guidance also apply.

1. Home IVIG Administration Items and Services Supplier Type

Section 4134(b) of the CAA, 2023 amends section 1842(o) of the Act by adding a new paragraph (8) that establishes a separate bundled payment to the supplier for all items and services related to the administration of such intravenous immune globulin, described in section 1861(s)(2)(Z) of the Act to such individual in the patient's home during a calendar day. Section 4134(c) of the CAA, 2023 amends section

[101] Updated Interim Report to Congress: Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration Project, August 2022 found at: *https://innovation.cms.gov/data-and-reports/2022/ivig-updatedintrtc.*

[102] *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794.*

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

1834(j)(5) of the Act, which are a requirement for supplier of medical equipment and supplies, by adding a new subparagraph (E), clarifying with respect to payment, that items and services related to the administration of intravenous immune globulin furnished on or after January 1, 2024, as described in section 1861(zz) of the Act, are included in the definition of medical equipment and supplies. This means that suppliers that furnish IVIG administration items and services must meet the existing DMEPOS supplier requirement for payment purposes under this benefit. Suppliers of IVIG administration items and services must enroll as a DMEPOS supplier and comply with the Medicare program's DMEPOS supplier standards (found at 42 CFR 424.57(c)) and DMEPOS quality standards to become accredited for furnishing medical equipment and supplies. Further, to receive payment for home IVIG items and services, the supplier must also meet the requirements under subpart A of part 424, Conditions for Medicare Payment. The DMEPOS supplier may subcontract with a provider to meet the professional services identified in section V.B.1. of this proposed rule. All professionals who furnish services directly, under an individual contract, or under arrangement with a DMEPOS supplier to furnish services related to the administration of IVIG in the home, must be legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State, and local laws, and must act only within the scope of their State license or State certification, or registration. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs or from any other Federal procurement or non-procurement programs.

2. Home IVIG Administration

Section 1861(s)(2)(Z) of the Act defines benefit coverage of intravenous immune globulin for the treatment of primary immune deficiency diseases *in the home.* Under the IVIG Demonstration, beneficiaries are eligible to participate if they receive IVIG services in ''their home or a setting that is 'home like' ''.[104] Section 410.12(b) identifies the supplier types who can furnish the services identified at § 410.10. Section 410.38 provides the conditions for payment for DME suppliers and identifies the institutions that may not qualify as the patient's home. As such, the home administration of IVIG items and services must be furnished in the patient's home, defined as a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, critical access hospital (CAH), or SNF as defined in § 410.38(b).

D. Home IVIG Items and Services Payment Rate

1. Proposed Payment Rate Update for Home IVIG Items and Services for CY 2025

Section 1842(o) of the Act provides the authority for the development of a separate bundled payment for Medicare-covered items and services related to the administration of intravenous immune globulin to an individual in the patient's home during a calendar day, in an amount that the Secretary determines to be appropriate. This section of the Act also states payment may be based on the payment established pursuant to section 101(d) of the Medicare IVIG Access Act. Section 4134(d) of the CAA, 2023, amends section 1833(a)(1) of the Act to provide that, with respect to items and services related to the administration of IVIG furnished on or after January 1, 2024, as described in section 1861(zz) of the Act, the amounts paid shall be the lesser of the 80 percent of the actual charge or the payment amount established under section 1842(o)(8) of the Act.

In accordance with section 101(d) of the Medicare IVIG Access Act, the Secretary established a per visit Demonstration payment amount for the items and services needed for the in-home administration of IVIG based on the national per visit low-utilization payment amount (LUPA) under the prospective payment system for home health services established under section 1895 of the Social Security Act. Under the Demonstration, the bundled payment amount for services needed for the home administration of IVIG included infusion services provided by a skilled nurse. Therefore, the bundled payment was based on the LUPA amount for skilled nursing, based on an average 4-hour infusion. The initial payment rate for the first year of the Demonstration, was based on the full skilled nursing LUPA for the first 90 minutes of the infusion and 50 percent of the LUPA for each hour thereafter for an additional 3 hours. Thereafter, the payment rate was annually updated based on the nursing LUPA rate for such year. The service was subject to coinsurance and deductibles similar to other Part B services.

We stated in the CY 2024 HH PPS proposed rule (88 FR 43755), we believed payment under section 1861(s)(2)(Z) of the Act covers the same items and services covered under the IVIG Demonstration. We also agreed that the professional services needed to safely administer IVIG in the home would be services furnished by a registered nurse (88 FR 43756). Therefore, we stated that setting the CY 2024 payment rate for the home IVIG items and services under section 1861(s)(2)(Z) of the Act, based on the CY 2023 payment amount established under the Demonstration was appropriate. However, we noted the Demonstration used the LUPA rate, which is annually adjusted by the wage index budget neutrality factor, as well as the home health payment rate update percentage, and stated that we believed it was appropriate to update the CY 2023 IVIG services Demonstration rate by only the CY 2024 home health payment rate update percentage. We stated that we would not include the wage index budget neutrality factor, as the IVIG items and services payment rate is not statutorily required to be geographically wage adjusted. Further, although section 1842(o) of the Act states that payment is for the items and services furnished to an individual in the patient's home during a *calendar day,* we stated that, as the statute aligns the payment amount with such amount determined under the Demonstration, we believed the best reading of ''calendar day'' is ''per visit.'' Additionally, we stated that we would expect a supplier to furnish only one visit per calendar day (88 FR 43756).

In the CY 2024 HH PPS final rule, we established a new subpart R under the regulations at 42 CFR part 414 to incorporate payment provisions for the implementation of the IVIG items and services payment in accordance with section 1842(o) of the Act for home IVIG items and services furnished on or after January 1, 2024. We finalized a policy at § 414.1700(a), that a single payment amount is made for items and services furnished by a DMEPOS supplier *per visit.* We finalized a policy at § 414.1700(b), setting the initial payment amount equivalent to the CY 2023 ''Services, Supplies, and Accessories Used in the home under the Medicare IVIG Demonstration'' payment amount, updated by the CY 2024 home health update percentage of 3.0 percent. We also finalized a policy at § 414.1700(c) to annually update the CY 2025 home IVIG items and services payment rate and subsequent years, by

[104] Intravenous Immune Globulin Demonstration MLN Fact Sheet: *https://www.cms.gov/files/document/mln3191598-intravenous-immune-globulin-demonstration.pdf.*

the home health payment rate update percentage for such year. Therefore, the proposed CY 2025 home IVIG items and services payment rate would be the CY 2024 IVIG items and services payment rate of $420.48 updated by the proposed home health payment update percentage of 2.5 percent ($420.48 * 1.025 = $430.99).

The updated home intravenous immune globulin items and services payment rate will be posted in the Billing and Rates section of the CMS' Home Infusion Therapy (HIT) web page (found at *https://www.cms.gov/medicare/payment/fee-for-service-providers/home-infusion-therapy*) once this rate is finalized. In subsequent years, if CMS does not intend to propose changes to its established methodology for calculating the IVIG items and services payment, this payment rate will be updated using CMS' established methodology via the Home Health Prospective Payment System Rate Update Change Request and posted on the CMS HIT/Home IVIG Services web page.[105] For more in-depth information regarding the finalized policies associated with the scope of the home IVIG items and services payment, we refer readers to the CY 2024 HH PPS final rule (88 FR 77791).

VI. Home Health CoP Changes and Long Term (LTC) Requirements for Acute Respiratory Illness Reporting

A. Home Health CoP Changes

1. Background and Statutory Authority

CMS has broad statutory authority to establish health and safety standards for most Medicare- and Medicaid-participating provider and supplier types. The Secretary gives CMS the authority to enact regulations that are necessary in the interest of the health and safety of individuals who are furnished services in an institution, while other laws, as outlined later, give CMS the authority to prescribe regulations as may be necessary to carry out the administration of the program. 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.

The CoPs apply to the HHA as an entity, as well as to the services furnished to each individual patient under the care of the HHA. In accordance with section 1861(o) of the Act, the Secretary is responsible for establishing additional CoPs besides those set out in the statute that are adequate to protect the health and safety of the individuals under HHA care. Section 1891(c)(2) of the Act establishes the requirements for surveying HHAs to determine whether they meet the CoPs.

2. Proposed Updates to the Home Health Agency CoPs To Require HHAs To Establish an Acceptance to Service Policy (§ 484.105(i))

Admission to HHA services is a critical step in the process of patients receiving timely, appropriate care to meet their needs. In accordance with the requirements of § 484.105(f)(1), each HHA must furnish skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, occupational therapy, medical social services, or home health aide services) on a visiting basis and in a place of residence that is used as a patient's home. As such, the services provided by each HHA vary, creating challenges for individuals seeking to find the right HHA to meet their unique care needs. Likewise, the unique mix of services provided by an HHA also necessitates an HHA-specific approach to accepting referrals for care to ensure that the HHA is capable of meeting the needs of the referred patient, in accordance with the requirements of § 484.60. This CoP states that patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's needs in his or her place of residence. Thus, a timely, appropriate admission process serves both prospective patients seeking care and ensures that HHAs accept for treatment only those patients for whom there is a reasonable expectation of being able to meet the patient's care needs.

Researchers have found that timely admission to home health, and in turn the initiation of services are key to good home health patient outcomes. Timely initiation of home health care lowers the risk of 30-day hospital readmissions.[107] According to one study published in 2021, when the initiation of home health services is significantly delayed (that is, from 8 to14 days after discharge), the odds of rehospitalization for diabetic patients were four times greater than among patients receiving home health service initiation within 2 days.[106] Yet the rate of timely initiation of home health care varies significantly, indicating that the referral and acceptance process is in need of improvement. In a study of initiation of home health care for individuals diagnosed with Alzheimer's disease and related dementia,[107] only 57.3 percent of patients discharged from the hospital began home health services within 48 hours of discharge, while 21.6 percent of patients had care initiated between 3 and 7 days post-discharge, another 8.4 percent had care initiated between 8–10 days post-discharge, and 12.8 percent experienced a delay of 11 to 14 days between discharge and home health care initiation. The 42.7 percent of patients in the study who waited 3 or more days after discharge for initiation of home health services were more likely to be dually enrolled in Medicare and Medicaid, live in rural areas, have experienced longer hospital stays, experienced a hospital acquired condition, or experienced an intensive care unit stay. Additionally, this population was more likely to have been discharged with a lower functional status and were more likely to live alone. In another study of Medicare beneficiaries,[108] only 54 percent of patients discharged from the hospital to home health care received home health care services within 14 days of discharge. The rate of patients receiving home health services within 14 days of discharge with a home health referral was even lower among Black and Hispanic patients, those who were dually enrolled in both Medicare and Medicaid, and patients who lived in high-poverty, high unemployment zip codes. This research brings attention to vulnerable populations at risk of poor outcomes associated with delays in the timely initiation of home health care services.[109]

Timely initiation of home health care services is also intrinsically linked to the home health referral process, whereby connections are made between referral sources and HHAs. Patient referral sources are varied, with some patients and caregivers conducting their own searches for care, known as self-referrals, while others are referred by a community-based practitioner or an acute care provider such as a hospital. Patients that begin HHA care without an

[105] *https://www.cms.gov/medicare/payment/fee-for-service-providers/home-infusion-therapy.*

[106] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8197411/,* date accessed 5–7–24.

[107] Amol M. Karmarkar, Indrakshi Roy, Taylor Lane, Stefany Shaibi, Julie A. Baldwin & Amit Kumar (2023), Home health services for minorities in urban and rural areas with Alzheimer's and related dementia, Home Health Care Services Quarterly, 42:4, 265–281, DOI: 10.1080/01621424.2023.2206368.

[108] Assessment of Receipt of the First Home Health Care Visit After Hospital Discharge Among Older Adults. Jun Li, Ph.D., Mingyu Qi, MS, and Rachel M. Werner, Ph.D., MD. JAMA Netw Open. 2020 Sep; 3(9): e2015470. doi: 10.1001/jamanetworkopen.2020.15470:10.1001/jamanetworkopen.2020.15470.

[109] *https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.13139,* date accessed 5–08–24.

immediate prior hospitalization, those who are self-referrals or referred by a community-based practitioner, tend to be Medicaid recipients, have cognitive impairments, and are more socially vulnerable (defined as the gap between patient needs and the patient's available resources) than patients admitted from acute care. Additionally, they tend to have received 80 or more hours per month of family caregiver assistance prior to their acceptance to HHA services.[110] This population has unique needs and circumstances needs that may make finding the right HHA a challenging process, and they may not have access to information needed to target their search for an HHA in an effective and efficient manner. Given the significant delays in home health care initiation described earlier and the role that this information plays in facilitating care initiation, we are concerned about this lack of public transparency and whether referral sources, including patients and caregivers searching for HHA services, currently have access to sufficient and timely information necessary to locate an HHA that is capable of meeting each specific patient's needs. Without such information, care delays are likely to occur, placing patients at higher risk of poor outcomes.

In addition to the challenges of finding the right HHA and resultant potential delays in the timely initiation of home health care, we are also concerned that HHAs are at higher risk of overextending their available resources when accepting new patients to HHA services. Delays in service initiation may indicate not only that referral sources have difficulty locating an appropriate HHA, but also that HHAs are accepting patients when and for whom they are not capable of delivering timely care. We are aware of anecdotal reports of home care agencies not providing care to meet patient needs [111] [112] and reports by agencies of challenges maintaining appropriate staff caseloads to continue delivering care to patients that have been accepted for service. We acknowledge that these challenges may be related to workforce shortages. HHAs are expected to discharge patients for whom the HHA is unable to deliver care to meet patient needs, and to adhere to the HHA discharge requirements at § 484.58. Such discharges create transition of care burdens for patients and their caregivers that may be prevented by consistently applying an admission to service policy that includes the elements proposed in this rule to ensure the correct match of an HHA's available patient care resources and the anticipated needs of the patients accepted for service by that HHA. In line with this HHA proposal, CMS recently published a final rule titled ''Ensuring Access to Medicaid Services'' (89 FR 40542, May 10, 2024), which requires States to report how they establish and maintain Home and Community Based Services (HCBS) wait lists, assess wait times, and report on quality measures. That final rule aims to increase transparency and accountability and standardize data and monitoring, with the goal of improving access to care.

To address these dual concerns regarding the referral and acceptance process and their implications for prospective and current patients, we propose to add a new standard at § 484.105(i) that would require HHAs to develop, implement, and maintain an acceptance to service policy that is applied consistently to each prospective patient referred for home health care. We propose to require that the policy be reviewed annually and address, at minimum, the following criteria related to the HHA's capacity to provide patient care: the anticipated needs of the referred prospective patient, the HHA's case load and case mix, the HHA's staffing levels, and the skills and competencies of the HHA staff. It is our understanding, based on information provided by HHA accrediting organizations and the largest HHA trade association, that HHAs typically have acceptance to service policies that are categorical in nature, meaning that the policies address entire categories of diagnosis or service types that they are or are not capable of providing care for. This proposed rule would not prevent HHAs from maintaining these existing policies and is intended to complement them. We also understand that an HHA's case load, case mix, and staffing levels may change over time, and that an HHA may choose to pre-establish methodologies that take into account such fluctuations as part of their acceptance to service policy to ensure consistency and minimize administrative efforts in maintaining the policy.

We propose, at § 484.105(i)(1)(i) through (iv), that HHAs would be required to include information regarding the HHA's case load and case mix (that is, the volume and complexity of the patients currently receiving care from the HHA), anticipated needs of the referred prospective patient, the HHA's current staffing levels, and the skills and competencies of the HHA staff. These proposed elements are designed to inform an HHA's assessment of its capacity and determine its suitability to meet the anticipated needs of the prospective patient that has been referred for HHA services. While all of a prospective patient's needs may not be known at the time of referral, general information regarding the patient's diagnosis and recent hospitalization (as appropriate), and specific orders from the patient's medical provider would provide a reasonable basis for HHAs to anticipate the overall needs of the patient and determine whether, in light of the described factors, the prospective patient is or is not appropriate for the HHA to accept for service. In accordance with § 484.60, HHAs may only accept those patients for whom there is a reasonable expectation that the HHA will be able to meet the patient's needs.

We therefore propose that the patient acceptance to service policy be applied consistently to ensure that HHAs only accept those patients for whom there is a reasonable expectation that the HHA can meet the referred patient's needs. Not only would consistent application of the acceptance to service policy help to ensure that HHAs only accept referrals for care that they can deliver, it would also ensure that HHAs apply their acceptance policy based on clinical and operational factors (those criteria included in proposed § 484.105(i)(1)(ii) through (iv)) that impact patient health and safety. While Medicare-participating HHAs may choose to accept other, non-Medicare sources of payment, we expect that HHAs would apply their acceptance to service policy consistently in a manner that is neutral to the source(s) of payment for a referral. That is, if an HHA accepts payment from both Medicare and another payment source, ''source X,'' the HHA's referral policy should be applied consistently to referrals for patients having Medicare or ''source X'' as a payment source. It is our position that HHAs should accept or decline patient referrals based solely on clinical considerations and the capacity of the HHA to safely and effectively deliver care to meet patient needs,

[110] Social Vulnerability and Medical Complexity Among Medicare Beneficiaries Receiving Home Health Without Prior Hospitalization, Julia G. Burgdorf, Ph.D., Tracy M. Mroz, OTR/L, Ph.D., and Jennifer L. Wolff, Ph.D. Innovation in Aging, 2020, Vol. 4, No. 6, 1–9 doi:10.1093/geroni/igaa049.

[111] Pandemic-Fueled Shortages of Home Health Workers Strand Patients Without Necessary Care, February 3, 2022, KFF Health News. *https://kffhealthnews.org/news/article/pandemic-fueled-home-health-care-shortages-strand-patients/.* Accessed March 12, 2024.

[112] Caregiver Needed: How the Nation's Workforce Shortages Make it Harder to Age Well at Home, September 2022, USAging. *https://www.usaging.org/Files/Workforce-Issues_508.pdf.* Accessed March 14, 2024.

rather than on financial factors related to the perceived adequacy of the payment rate that the HHA has already voluntarily agreed to accept upon establishment of relationships with its payment sources.

We also propose, at § 484.105(i)(2), that HHAs make public accurate information regarding the services offered by the HHA and any limitations related to the types of specialty services, service duration, or service frequency, and that HHAs review that information annually or as necessary. As previously discussed, HHAs have the flexibility to choose the services that they provide and the geographic areas that they serve. As such, each HHA may provide a different mix of services or offer different specialty services. Likewise, each HHA has different geographical boundaries for its service area. Knowing which areas are served by an HHA and which services an HHA does and does not provide would assist referral sources and self-referrals alike in identifying HHAs that provide the services needed by the patient. Likewise, each HHA has unique staffing levels and staffing competencies affecting its capacity to deliver patient care, and those may change over time. To the extent that these variations in staffing impact the capacity of an HHA to provide its typically offered services, we would require that HHAs make public such limitations on specialty services, service duration, and service frequency to further inform the search efforts of all referral sources.

In short, making information regarding the services offered by the HHA and any limitations related to the types of specialty services, service duration, or service frequency available to the public, such as sharing it on the HHA's website and providing the same information upon request for those without access to the website, would facilitate the search for an HHA to meet a patient's needs, both from clinical referral sources such as hospitals and physician offices, and from patients and caregivers directly seeking care. The goal of this proposal is to reduce the delay between the time when a patient is identified as needing home health care and the time when the patient begins receiving such care by making key information readily available, thus improving identification of HHAs capable of meeting patient needs. Reducing the time delay would improve patient outcomes, as longer delays between referral and the initiation of HHA care are more likely to result in 30-day rehospitalizations and may place vulnerable populations at risk for various other adverse outcomes.

We request public comment on these proposals. Specifically, we request comment on alternative ways to address the delay of home health care initiation, barriers for patients with complex needs to find and access HHAs, and other opportunities to improve transparency regarding home health patient acceptance policies to better inform referral sources. We also request public comment regarding other ways to improve the referral process for referral sources, patients, and HHAs.

3. Requests for Information

a. RFI Regarding Rehabilitative Therapists Conducting the Initial and Comprehensive Assessment

The current CoPs at § 484.55(a)(1) require the registered nurse to conduct an initial assessment visit to determine the immediate care and support needs of the patient within 48 hours of referral, within 48 hours of the patient's return home, or on the physician allowed practitioner-ordered start of care date. The initial assessment establishes a patient's eligibility for coverage under the Medicare home health benefit. The clinician conducting the initial visit should determine the patient's homebound status, primary physician, and skilled services required. Section 484.55(b) further requires that the comprehensive assessment must be completed in a timely manner by a registered nurse, but no later than 5 calendar days after the start of care. However, when therapy services are the sole services ordered by the physician or allowed practitioner, the initial and comprehensive assessments can be conducted by rehabilitation professionals (specifically occupational therapists (OT), physical therapists (PT), or speech-language pathologists (SLP)), subject to certain limitations, as specified by § 484.55(a)(2) and (b)(3).

Section 484.55(c) establishes the minimum content of the comprehensive assessment, which must accurately reflect the patient's status and include the patient's current health, psychosocial, functional, and cognitive status. The comprehensive assessment must also reflect the patient's strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress towards the achievement of the goals identified by the patient and the measurable outcomes identified by the HHA. Additionally, the comprehensive assessment must include a determination of the patient's continuing need for home care, and their medical, nursing, rehabilitative, social, and discharge planning needs. Further, the comprehensive assessment must also include a review of the patient's medication and identify the patient's primary caregiver(s) or patient representative. Lastly, the comprehensive assessment must incorporate the current version of the Outcome and Assessment Information Set (OASIS) items. HHAs must complete data collection for the comprehensive assessment within 5 days of the start of care.

At the beginning of the COVID–19 Public Health Emergency (PHE), CMS waived the requirements at § 484.55(a)(2) and (b)(3) and thus permitted rehabilitation professionals to perform the initial and comprehensive assessment in instances when both nursing and therapy services are ordered. This temporary blanket waiver reflected the unique circumstances of the PHE, with its acute pressures on the nursing workforce, and allowed rehabilitation professionals to perform the initial and comprehensive assessment for patients receiving therapy services as part of the broader nursing and therapy care plan, to the extent permitted under State law, regardless of whether the therapy service established patient eligibility to receive home care.

Subsequently, Division CC, section 115 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), permitted OTs to conduct the initial and comprehensive assessments only when OT is on the home health plan of care with either PT or speech therapy, and skilled nursing services are not initially on the plan of care. CMS proposed changes to § 484.55(a)(3) and (b)(2) in the CY 2022 Home Health PPS proposed rule (86 FR 35874), and finalized the changes in the CY 2022 Home Health PPS final rule (86 FR 62240).

However, some groups continue to advocate for CMS to permanently allow therapists to perform the initial and comprehensive assessment in the home health setting when both therapy and nursing services are ordered. While CMS received limited feedback during the CY 2022 Home Health PPS proposed rule from several commenters supporting a change of this type, we are interested in obtaining additional feedback on this specific potential change.

The three types of rehabilitative therapists (OT, PT, and SLP) have different education requirements for entry into to practice. Currently, entry-level education for OT is either a Master's degree or Doctorate of Occupational Therapy. Education programs are accredited by the Accreditation Council for Occupational

Therapy Education (ACOTE) of the American Occupational Therapy Association (AOTA). The ACOTE establishes, approves, and administers educational standards to evaluate occupational therapy educational programs. Graduates of ACOTE-accredited programs are eligible to take the National Board for Certification in Occupational Therapy (NBCOT) certification exam and apply for State licensure.

Physical therapy entry-level education requires a Doctor of Physical Therapy degree. The Commission on Accreditation in Physical Therapy Education (CAPTE) of American Physical Therapy Association (APTA) accredits entry-level physical therapist education programs. Graduates of these programs are then eligible to take the National Physical Therapy Examination and apply for State licensure.

Speech Language Pathologists must obtain a Certificate of Clinical Competence in Speech-Language Pathology (CCC–SLP) as well as state licensure. This requires graduation from a program accredited by the Council on Academic Accreditation in Audiology and Speech-Language Pathology (CAA) of the American Speech-Language-Hearing Association (ASHA). Individuals applying for certification in speech-language pathology must have been awarded a master's, doctoral, or other recognized post-baccalaureate degree. Once students complete all academic coursework and a graduate student clinical practicum, they must also complete a clinical fellowship under the supervision of a SLP mentor. The clinical fellowship requires working at least 36 weeks and 1,260 hours and is intended to transition the fellow from a student enrolled in a communication sciences and disorders (CSD) program to an independent provider of speech-language pathology clinical services.

The APTA has indicated that the accreditation standards for entry-level certification programs for physical therapy have evolved over time, with major changes occurring between 1996 and 2024, and that contemporary PT education programs are now required to include content for students on broader health care issues to promote team-based and interdisciplinary practice. The association states that the current criteria reflect that PT education has shifted significantly since the initial and comprehensive assessments were codified into the home health CoPs, preparing any PT to perform these assessments safely. APTA further contends that education standards have shifted from an initial focus on physical sciences to expressly incorporate interdisciplinary care topics, including pharmacology and psychosocial, and clinical educational experience in practice settings common to PTs (for example, HHAs, skilled nursing facilities (SNFs), and inpatient rehabilitation facility (IRFs)). The curricular requirements include the general clinical skills required to conduct the initial and comprehensive assessments, both in the identification of immediate care and support needs, as well as the assessment of the patient's general health, psychosocial, functional, cognitive, and pharmacological status.

Given recent input from stakeholders, including therapy professional organizations, we seek public comments regarding whether CMS should shift its longstanding policy and permit all classes of rehabilitative therapists (PTs, SLPs, and OTs) to conduct the initial assessment and comprehensive assessment for cases that have both therapy and nursing services ordered as part of the plan of care. We ask the public for data, detailed analysis, academic studies, or any other information to support their comments that provide a direct link to patient health and safety. Specifically, we solicit comment regarding the following:

- What types of mentorships, preceptorship, or training do these disciplines have qualifying them to conduct the initial assessment and comprehensive assessment?
- How do HHAs currently assign staff to conduct the initial assessment and comprehensive assessment? Do HHAs implement specific skill and competency requirements?
- Do the education requirements for entry-level rehabilitative therapist provide them with the skills to perform both the initial assessment and comprehensive assessment? Is this consistent across all the therapy disciplines? How does this compare with entry-level education for nursing staff?
- What, if any, potential education or skills gaps may exist for rehabilitative therapists in conducting the initial assessment and comprehensive assessment?
- What challenges did HHAs and therapists that conducted these assessments under the PHE waiver experience that may have impacted the quality of these assessments?
- For the HHAs and therapists that conducted the initial assessment and comprehensive assessment under the PHE waiver, what were the benefits and were there any unintended consequences of this on patient health and safety?
- What challenges, barriers, or other factors, such as workforce shortages, particularly in rural areas, impact rehabilitative therapists and nurses in meeting the needs of patients at the start of care and early in the plan of care?

b. Plan of Care Development and Scope of Services Home Health Patients Receive

In an effort to improve the HHA referral process, ensure the timely delivery of home health care, and ensure that home health care is delivered in a manner that meets patient needs and achieves the measurable outcomes and goals set forth in each patient's individualized plan of care, we are requesting public comment on policies related to these goals. Anecdotally, CMS has received an increasing number of beneficiary complaints related to the difficulty of finding a HHA to accept them for service. Beneficiaries complain that in some instances, HHA services are being altered or diminished from the original plan of care without an accompanying reduction in patient needs or achievement of the measurable outcomes and goals set forth in the plan of care. We seek to better understand these issues to inform future policy decisions, consistent with our statutory authority to ensure the health and safety of home health patients.

In CY 2022 Home Health PPS proposed rule, we solicited comments seeking information about the adequacy of aide staffing (86 FR 35874, July 7, 2021). However, only a few commenters provided information specific to the questions we posed in our request. This information was not sufficient to gain insight to the factors that may be impacting the decline in aide services. No further development action was taken due to the lack of substantive data and response from stakeholders.

The number of referrals to HHAs continue to increase. Patient acuity is also increasing [113] [114] with the evolving practice of direct discharge of intensive care unit (ICU) patients, a practice borne out of resource constrained health care infrastructure.[115] Compared to 2019 averages, patients are 6 percent more acute at discharge. Patients with higher acuity typically have more complex care needs and a higher risk of

[113] The evolution of care: An annual care delivery report, from CarePort, powered by WellSky, 2023.

[114] *https://www.fiercehealthcare.com/providers/hospitals-struggling-discharge-patients-post-acute-care-settings-wellsky-report#:~:text=Patients%20in%20the%20hospital%20are,post%2Dacute%20settings%20more%20difficult.*

[115] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9750104/.*

complications.[116] [117] The overall aging of the U.S. population contributes to overall higher patient acuity. The U.S. Census Bureau estimated that by 2023 73 million baby boomers in the U.S. will be 65 or older. Chronic conditions are more common in older adults and can contribute to higher acuity.[118] [119] In addition, procedures that were once traditionally done in hospitals are migrating to the outpatient setting and patients are being discharged on the same day as the procedure. Specifically, surgical procedures within the U.S. are increasingly shifting to outpatient or non-hospital locations, as seen in the expected 4 percent annual expansion rate of the ambulatory surgery center (ASC) market over the 10-year period from 2017 to 2027.[120] For example, the incidence of total knee arthroplasty (TKA) surgery performed in the outpatient setting has increased as a result of improved perioperative recovery protocols and challenges brought by the COVID–19 pandemic on health systems.[121] Further, literature shows that factors like the pandemic and ''acuity creep'' have resulted in HHAs accepting for service much more complicated patients. ''As the demand for home-based care continues to rise, so does the need for more intensive care plans as patients continue to be sicker and more complex.'' [122]

We acknowledge that there may be additional factors, such as the shortage of health care practitioners (nurses and aides) across various health care sectors, and HHA business operations and practices that also influence an HHA's care planning and delivery of services. We seek to understand the changes in practice that have occurred since publication of the January 13, 2017 ''Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies'' final rule that revised the home health agency CoPs (82 FR 4504) and review any potential CoP revisions that should be considered. In order to protect the health and safety of all HHA patients, we seek to understand how the services offered and business operations of the HHA may influence the development and implementation of care plans. We are also seeking additional information on how HHAs communicate with patients' ordering physicians and allowed practitioners regarding the frequency and duration of services.

We are seeking public comments on factors that influence the services HHAs provide, the referral process, limitations on patients being able to obtain HHA service, such as rural location and availability of staff, plan of care development, and the HHA's communication with patients' ordering physicians and allowed practitioners. We ask the public for data, detailed analysis, academic studies, or any other information to support their comments that provide a direct link to patient health and safety. Specifically, we solicit comment regarding the following questions:

- What factors influence an HHA's decision on what services to offer as part of its business model and how often do HHAs change the service mix?
- What are the common reasons for an HHA to not accept a referral?
- How do physicians and allowed practitioners use their role in establishing and reviewing the plan of care to ensure patients are receiving the right mix, duration, and frequency of services to meet the measurable outcomes and goals identified by the HHA and the patient?
- To what extent do physicians rely on HHA clinician evaluations and reports in establishing the mix of services, service frequency, and service duration included in the plan of care?
- What are the patient and caregiver experiences in receiving nursing, aide, and therapy services when under the care of a home health agency?
- What additional evidence is available regarding negative outcomes or adverse events that may be attributable to the mix, duration, and service frequency provided by HHAs, including, but not limited to, avoidable hospitalizations?
- In what ways can referring providers and HHAs improve the referral process?
- What other factors may influence the provision of services that impact the timeliness of services and service initiation?
- What additional areas should CMS consider to address HHA patient health and safety concerns?

B. Long-Term Care (LTC) Requirements for Acute Respiratory Illness Reporting

1. Background

Under sections 1866 and 1902 of the Act, providers of services seeking to participate in the Medicare or Medicaid program, respectively, must enter into an agreement with the Secretary or the State Medicaid agency, as appropriate. Long-term care (LTC) facilities seeking to be Medicare and Medicaid providers of services must be certified as meeting Federal participation requirements. LTC facilities include skilled nursing facilities (SNFs) for Medicare and nursing facilities (NFs) for Medicaid. The Federal participation requirements for SNFs, NFs, and dually certified facilities, are set forth in sections 1819 and 1919 of the Act and codified in the implementing regulations at 42 CFR part 483, subpart B.

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents. Continuous and systematic collection of data is an essential component of any infection control program, as the data provides information about potential health threats and enables prevention planning to mitigate severe health outcomes. LTC residents are vulnerable to infection from SARS–CoV–2 because of chronic health conditions, immunosenesence, and residence in a communal living setting. Vaccination provides protection against infection but does not eliminate the risk of acquiring SARS–CoV–2. Epidemiologic data from the CDC's National Healthcare Safety Network (NHSN) indicate that weekly COVID–19 cases continue to follow the general surge patterns of 2020 to 2023, despite the vaccination status of the nursing home population. Additionally, the U.S. population remains at risk of increased infection incidence and adverse outcomes as additional SARS–CoV–2 strains continue to emerge, and immunity induced by COVID–19 vaccines wane. As such, in alignment with the sections 1819(d)(3), 1919(d)(3), 1819(d)(4)(B), and 1919(d)(4)(B) of the

[116] The evolution of care: An annual care delivery report, from CarePort, powered by WellSky, 2023.

[117] *https://www.fiercehealthcare.com/providers/hospitals-struggling-discharge-patients-post-acute-care-settings-wellsky-report#:~:text=Patients%20in%20the%20hospital%20are,post%2Dacute%20settings%20more%20difficult.*

[118] *https://www.fiercehealthcare.com/providers/hospitals-struggling-discharge-patients-post-acute-care-settings-wellsky-report#:~:text=Patients%20in%20the%20hospital%20are,post%2Dacute%20settings%20more%20difficult.*

[119] *https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html.*

[120] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10562071/#:~:text=Surgical%20procedures%20within%20the%20United,In%202018%2C%20Young%20et%20al.*

[121] *https://josr-online.biomedcentral.com/articles/10.1186/s13018-023-03750-4.*

[122] *https://homehealthcarenews.com/2024/01/home-health-agencies-grapple-with-acuity-creep-as-patient-needs-become-more-complex/.*

Act, the policy proposed in this regulation to establish the ongoing collection of the proposed set of data elements is necessary to quickly identify threats to resident health and safety and initiate requisite responses. The data proposed in this regulation for ongoing collection would support facility, State, and Federal-level public health actions that protect the health and safety of residents and ongoing response efforts. In addition, the data collected would continue to be supplied directly to LTC facilities, State health departments, the CDC, and CMS to detect infection outbreaks, monitor the impact of infection prevention strategies, and vaccination uptake (sections VI.B.2. through B.5. of this proposed rule outline specific benefits because of the proposed data collections).

Infection prevention and control in LTC facilities was especially important during the COVID–19 PHE. Under the explicit instructions of Congress, existing regulations at § 483.80 require facilities to, among other things, establish and maintain an infection prevention and control program (IPCP) designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. The COVID–19 PHE placed enormous strain on the Nation's healthcare systems, requiring LTC facilities nationwide to take extraordinary measures in the face of staff shortages, and the scarcity of personal protective equipment (PPE) and critical supplies. Protecting residents in these circumstances demanded that we have better visibility and data on the spread and impact of COVID–19 in the Nation's LTC facilities. In response, CMS issued an evolving series of requirements to obtain those data through several interim final rules with comment period (IFC) during the height of the PHE and subsequent final rules to support ongoing efforts to monitor and protect residents against COVID–19. When the CDC started collecting COVID–19 case data on a national scale in LTC facilities we began to understand the epidemiological trends of COVID–19 disease in LTC residents. The data highlighted how LTC facilities played a large role in viral transmission and that LTC residents were disproportionally impacted by COVID–19 compared to community dwelling adults. Even after the end of the PHE, national data collected in LTC facilities has shown that LTC residents continue to be impacted by COVID–19 at higher rates than older adults in the community and are more likely to develop severe outcomes. Continuing to understand trends of COVID–19 and other significant respiratory diseases (for example, RSV, Influenza) in the LTC population is critical to understanding the burden of respiratory viruses on the country.

First, on May 8, 2020, we issued a IFC titled ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' (85 FR 27550), which revised the infection prevention and control requirements for LTC facilities to more effectively respond to the specific challenges posed by the COVID–19 pandemic. Specifically, this May 2020 IFC added provisions to require facilities to electronically report information related to confirmed or suspected COVID–19 cases to the Centers for Disease Control and Prevention (CDC) and required facilities to inform residents and their representatives of confirmed or suspected COVID–19 cases in the facility among residents and staff.

Second, on September 2, 2020, we issued a IFC titled ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act, Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (85 FR 54873). This September 2020 IFC set out provisions regarding testing for COVID–19 in LTC facilities, including documentation requirements and protocols specifying actions to be taken if a resident or staff member tests positive. On May 13, 2021, we issued another IFC titled ''Medicare and Medicaid Programs; COVID–19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff'' (86 FR 26306), which further revised the infection control requirements that LTC facilities and intermediate care facilities for individuals with intellectual disabilities (ICFs-IID) must meet to participate in the Medicare and Medicaid programs. This May 2021 IFC aimed to reduce the spread of SARS–CoV–2 infections, the virus that causes COVID–19, by requiring education about COVID–19 vaccines for LTC facility residents, ICF–IID clients, and staff serving both populations, and by requiring that such vaccines, when available, be offered to all residents, clients, and staff. It also required LTC facilities to report COVID–19 vaccination status of residents and staff to CDC.

To retain the data reporting requirements after the end of the PHE, on November 9, 2021, we subsequently published a final rule titled ''CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID–19 Reporting Requirements for Long-Term Care Facilities'' (86 FR 62421), which finalized the COVID–19 data reporting requirements from the May 2020 and May 2021 IFCs. Specifically, in this November 2021 final rule, we revised the requirements at § 483.80(g)(1)(i) through (ix), to reduce the burden on the LTC facilities by allowing for a reduced frequency of reporting (weekly unless the Secretary specifies a lesser frequency) and modified the specific data elements to be reported. The rule states that until December 31, 2024, facilities must electronically report, in a standardized format specified by the Secretary, information on suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19, total deaths and COVID–19 deaths among residents and staff, personal protective equipment and hand hygiene supplies in the facility, ventilator capacity and supplies available in the facility, resident beds and census, access to COVID–19 testing while the resident is in the facility, and staffing shortages. In addition, on an ongoing basis with no sunset date, facilities are required to report information on resident and staff vaccination status for COVID–19.

Finally, on June 5, 2023, we issued a final rule titled ''Medicare and Medicaid Programs' Policy and Regulatory Changes to the Omnibus COVID–19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for LTC Facilities and ICF–IIDs to Provide COVID–19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the LTC Facility COVID–19 Testing Requirements'' (88 FR 36485).[123] This June 2023 final rule

[123] June 2023 Final Rule. *https://www.govinfo.gov/content/pkg/FR-2023-06-05/pdf/2023-11449.pdf.*

removed expired language addressing COVID–19 testing requirements issued in the September 2020 IFC, withdrew requirements mandating COVID–19 vaccinations for staff (see 86 FR 61555 for details regarding the IFC that issued the requirements),[124] and finalized requirements issued in the May 2021 IFC for facilities to provide education about vaccines and to offer COVID–19 vaccines to residents and staff.

2. The Benefits of and Ongoing Need for LTC Facility Respiratory Illness and Vaccination Data

There are over 1.3 million older adults aged 65 years and older living in LTC facilities in the United States; and while LTC facility residents make up less than 0.5 percent of the population in the U.S., they were estimated to account for between 23 percent and 40 percent of deaths due to COVID–19 in the first two years of the COVID–19 PHE.[125] [126] Older residents are at greater risk for both developing COVID–19 and other respiratory illnesses (for example, influenza, RSV) and for developing a protracted course of disease.[127] Age-associated changes in immune function (that is, immunosenecense) can increase susceptibility to infection and decrease response to vaccination. Additionally, older adults often have multiple co-morbidities leading to increased morbidity and mortality when coupled with a respiratory tract infection.[128] The congregate setting of LTC facilities can also increase risk of disease transmission given the proximity of residents. In addition, providing care for residents often involves close-contact activities (for example, dressing, bathing) and the same health care personnel provide care to residents across different rooms and shared spaces. This readily facilitates transmission of respiratory viruses in this setting.[129] Furthermore, LTC facility staffing shortages and consistent staff turnover, that are ever-present, but were greatly exacerbated during the COVID–19 PHE, make it even more challenging to provide quality care and to implement infection practices effectively and consistently, demonstrating the need for timely and actionable surveillance.[130]

The COVID–19 PHE highlighted the value and potential utility of greater integration between public health and health care, particularly when data are available to direct collaborative actions that support patient, resident, and public health and safety. Data from health care providers, including LTC facilities, remain a key driver to identify and respond to patient, resident, and public health threats, yet health care and public health data systems have long persisted on separate, often poorly compatible tracks.[131] The COVID–19 PHE also highlighted the importance of taking a broader view of patient and resident safety—one that recognizes patient and resident safety is determined not only by what is happening at the bedside, but also what is happening, in the facility as a whole, in neighboring facilities (for example, individuals moving between hospitals and LTC facilities and health care providers working in multiple facilities), and across the region, State, and county. The value of this broader view was particularly evident from the experience of LTC facilities, where systematic communicable disease and vaccination surveillance had never been integrated.

For the first time, during the COVID–19 PHE, the nation had a real-time comprehensive picture of a disease, its vaccine, and its impact in the nearly 16,000 U.S. LTC facilities because of data reported to the CDC's NHSN application. Ultimately, access to this information proved critical to providing resources and supporting coordinated action by facilities, health systems, communities and jurisdictions in responding to the PHE and protecting the health, safety and lives of LTC facility residents.

3. Benefits of Data Collection at the Facility and Local Level

The resources made available during the PHE response helped build resilience in some parts of the health care system, but the pandemic also exacerbated sources of fragility that continue to leave the United States underprepared to respond to surges—even relatively typical ones. Efforts to support the LTC community and facility infrastructure include the CMS final rule titled ''Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting,'' published on May 10, 2024 (89 FR 40876).[132] This final rule established a consistent floor (baseline) for nurse staffing across all LTC facilities in an effort to reduce the variability in nurse staffing. The final rule policies aim to advance equitable, safe, and quality care for all residents receiving care from the Nation's Medicare and Medicaid participating LTC facilities. The finalized minimum staffing standards coupled with the respiratory illness data reporting requirements proposed in this rule would support targeted high-quality care for residents. For example, timely and actionable surveillance at the facility and local level would support efforts to identify and allocate resources to maintain the appropriate care needed to keep residents safe.

Data collected from LTC facilities is used by local health departments to provide specific outreach to individual facilities. This can include interventions such as site visits from health departments, providing additional supplies such as PPE and/or testing supplies, recommendations for testing protocols and individualized advice for infection prevention and control practices to protect the health and safety of residents within individual facilities. LTC facilities care for some of the most vulnerable older adults who are disproportionally impacted by respiratory viruses and severe outcomes, such as hospitalizations and death. Ongoing data collection as part of a facility infection prevention and control program helps each facility to promptly identify a respiratory viral outbreak so that containment and important interventions, such as early anti-viral treatment (SARS–CoV–2, Influenza) and anti-viral prophylaxis (Influenza), can minimize the severity of an outbreak and protect residents' health and safety. Identifying strategies to provide early

[124] COVID–19 Health Care Staff Vaccination Interim Final Rule. *https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination.*

[125] Grabowski DC, Mor V. Nursing Home Care in Crisis in the Wake of COVID–19. JAMA. 2020;324(1):23. doi:10.1001/jama.2020.8524.

[126] Chidambaram P. Over 200,000 Residents and Staff in Long-Term Care Facilities Have Died From COVID–19. Kaiser Family Foundation. Published online February 3, 2022. *https://www.kff.org/policy-watch/over-200000-residents-and-staff-in-long-term-care-facilities-have-died-from-covid-19/.*

[127] The New York Times. Nearly One-Third of U.S. Coronavirus Deaths Are Linked to Nursing Homes. *https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html.* Published June 1, 2021.

[128] Vital and Health Statistics, Series 3, Number 47 (*cdc.gov*) (*https://www.cdc.gov/nchs/data/series/sr_03/sr03-047.pdf*).

[129] MMWR, Rates of COVID–19 Among Residents and Staff Members in Nursing Homes—United States, May 25–November 22, 2020 (*cdc.gov*) (*https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e2-H.pdf*).

[130] Infection prevention and control in nursing homes during COVID–19: An environmental scan—PMC (*nih.gov*) (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8810224/*).

[131] Vital and Health Statistics, Series 3, Number 47 (*cdc.gov*) (*https://www.cdc.gov/nchs/data/series/sr_03/sr03-047.pdf*).

[132] *https://www.govinfo.gov/content/pkg/FR-2024-05-10/pdf/FR-2024-05-10.pdf.*

antiviral treatments for COVID–19 and influenza may also help prevent more serious outcomes in individual residents.

Like other settings where health care is delivered, LTC facilities are part of an ecosystem caring for individuals in their community. This interdependency is especially highlighted during times of health care system strain. Insight into LTC facility capacity helps ensure capabilities are available to meet health care needs with quality care through enhanced planning, technical assistance, resource allocation, and coordination.[133] Health care coalitions (HCCs) are one example of local health care partners working together to increase local health care resilience during respiratory illness surges and more.[134] HCCs plan and respond together, sharing real-time information and providing technical assistance to support their partners.[135] Collaborative, data-driven approaches have helped to inform and direct action throughout the health care ecosystem, ultimately improving resident care and outcomes.

Data from LTC facilities is an important component to understanding potential bottlenecks in the health care ecosystem and ways to address them. During the COVID–19 PHE, hospitals struggled with being able to discharge patients to post-acute care, specifically LTC facilities. The availability of LTC facility capacity data helped to inform their response by monitoring triggers for patient load balancing, allocations of scarce resources, and requests for additional resources or mutual aid.[136] LTC facilities, hospitals, and other health care partners also use the information for planning purposes, identifying how their facility may be impacted and preparing accordingly.[137] Information sharing across the health care ecosystem helps the health care community to prepare for, and effectively respond to, respiratory illness surges in ways that maintain the safety and availability of critical care services.

Additionally, since the start of the PHE, data reported under our requirements at § 483.80(g)(1) through (3) have been used by LTC facilities and their local health systems to take actions aimed at protecting residents. Facilities can view all reported data and generate reports within the CDC's NHSN application. This allows facilities to review their data in real time and implement any applicable mitigation strategies/infection control practices, based on the counts they are seeing to help reduce outbreak occurrences. LTC facilities have used the CDC's NHSN dashboards and reports to track new cases and up-to-date vaccination status of residents in the facility and take action by identifying areas where they need to strengthen infection and control practices, explore vaccination progress, and consider targeted quality improvement activities as part of their Quality Assurance and Performance Improvement (QAPI) initiatives. LTC facilities can use NHSN to create custom data reports and analyses, tailoring the information for purposes and improvements that best meet their needs for protecting the residents in their care.[138]

4. Benefits of Data Collection at the Regional and State Levels

COVID–19 and other respiratory illness case, hospitalization, and vaccination data together provide critical situational awareness for regional and State leadership to inform a national strategy in response to the ongoing public health threat that respiratory illnesses including COVID–19 pose to residents. At the State and regional levels, public health departments and Quality Improvement Organizations (QIOs) have used these data to provide outreach and technical support directly to LTC facilities with high case and hospitalization counts and offer additional resources and support. QIOs use COVID–19 case and vaccination data to identify LTC facility outbreaks, provide 1:1 infection control assistance, and direct any other COVID–19 reduction assistance requested by those nursing homes. These data will continue to be critical to support the ongoing work of the QIOs. They will plan and provide technical assistance and training to LTC facilities identified by CMS for performance improvement based on quality measurement and enforcement data. The QIOs will also work on strengthening the quality management systems in LTC facilities, leadership and governance, culture of safety, workforce planning and focused clinical outcomes. Additionally, resident vaccination data direct the education and assistance efforts of partners like the QIOs and LTC associations to improve vaccination uptake in facilities with the lowest up-to-date vaccination rates among residents and staff. For example, the Nursing Home Command Center, in charge of directing QIOs, reviews NHSN COVID–19 case and vaccination data daily and considers NHSN data to be the best source to identify nursing homes in need of assistance to improve resident outcomes.[139]

In July 2020, the Federal Government launched a strike team initiative to address COVID–19 outbreaks in LTC facilities. This initiative relied upon data reported by LTC facilities to focus response efforts on the facilities with the highest number of cases. The Federal strike team initiative highlighted significant challenges faced by facilities and was foundational in identifying areas of infection prevention and control need, such as education for front line nursing staff, staffing shortages, and coordination among Federal State and local entities.[140] These efforts further emphasized that without data to direct assistance to places with the greatest need, response efforts and the limited resources, especially in non-emergency times of typical disease transmission, would be dispersed and far less effective. Building upon the 2020 Federal strike team efforts, a total of $500 million, was made available in 2021, through Sections 9402 and 9818 of the American Rescue Plan (ARP) Act of 2021, Public Law 117–2, to State and local health departments through the CDC's Epidemiology and Laboratory Capacity (ELC) Cooperative Agreement (CK19–1904), as the ''Nursing Home & Long-term Care Facility Strike Team and Infrastructure Project.'' This funding allowed States to continue dedicated support to LTC facilities and was used to build and maintain the infection prevention infrastructure necessary to

[133] *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/Kentucky-Collaborates-Community.aspx.*

[134] *https://aspr.hhs.gov/HealthCareReadiness/HealthCareReadinessNearYou/Documents/HCC-FactSheet-April2021-508.pdf.*

[135] *https://aspr.hhs.gov/HealthCareReadiness/HealthCareReadinessNearYou/Documents/HCC-FactSheet-April2021-508.pdf.*

[136] Mitchell SH, Rigler J, Baum K. Regional Transfer Coordination and Hospital Load Balancing During COVID–19 Surges. *JAMA Health Forum.* 2022;3(2):e215048. doi:10.1001/jamahealthforum.2021.5048. *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/HCC-Regional-Approach-Illinois.aspx.*

[137] *https://aspr.hhs.gov/HealthCareReadiness/StoriesfromtheField/Pages/Stories/Maryland-HCC-covid19.aspx.*

[138] Coverage with Influenza, Respiratory Syncytial Virus, and Updated COVID–19 Vaccines Among Nursing Home Residents—National Healthcare Safety Network, United States, December 2023 | MMWR (*cdc.gov*) (*https://www.cdc.gov/mmwr/volumes/72/wr/mm7251a3.htm*).

[139] Report to Congress, November 2023, for Fiscal Year 2022, The Administration, Cost, and Impact of the Quality Improvement Organization Program for Medicare Beneficiaries (*https://www.cms.gov/files/document/final-fy-2022-qio-rtc.pdf*).

[140] Protecting Nursing Home Residents from Covid–19: Federal Strike Team Findings and Lessons Learned | NEJM Catalyst (*https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0144*).

support resident, visitor, and facility healthcare personnel safety. State and local strike teams illustrated the power of public health and healthcare stakeholders working together to share data and information and collaborate effectively respond to respiratory illness surges. Between August 2021 and July 2022, health departments conducted over 26,000 Nursing Home COVID–19 responses, including more than 5,000 onsite assessments and more than 5,000 investigations that included staff supported specifically by Strike Team funding. For example, States like Massachusetts have lauded the value of the strike team investments and asserted that improved State and Federal data infrastructure is needed to respond to future outbreaks and protect nursing home residents.[141]

5. Benefits of Data Collection at the Federal Level

At the Federal level, the CDC actively uses weekly NHSN data reports to provide direct outreach to LTC facilities with >8 COVID–19 hospitalizations and >20 cases. These weekly reports are sent to State health departments to provide actionable data including confirmed COVID–19 cases among residents and staff, COVID–19 related deaths among residents, COVID–19 hospitalizations among residents, vaccine coverage among residents and staff, and COVID–19 potential outbreak alerts among other data elements. CDC also monitors downloads of these reports and provides ongoing support to States and facilities with these data, showing that the data are actively being used and are found to be valuable to direct response and vaccination efforts to the LTC facilities that most need support and intervention. For example, vaccination data are critical for decision making, targeting outreach for vaccination campaigns efforts, insights into vaccination disparities [142] and for vaccine effectiveness studies.[143] The availability of vaccination data from LTC facilities, not only provides a window into national efforts for improving access to vaccines for the LTC industry, but also can indicate the effectiveness of vaccination training and education efforts with residents and families, that promote the benefits of vaccination to help ensure that residents will achieve the best outcome possible if infected with the SARS–CoV–2 virus.

NHSN data has also been used by the CDC and QIOs to contact facilities with high vaccination coverage to understand the successful strategies they employed and promote these strategies to other nursing homes via webinars and the development of tools and resources. Information from this outreach was used to identify and respond to vaccination barriers by creating tools and resources, such as the Healthcare Provider Toolkit, to help nursing homes educate their staff, residents, and families to remove barriers to vaccination.

Furthermore, COVID–19, influenza, and RSV vaccination data continue to be used for establishing policies that promote better protection for residents and staff. These data continue to serve as supporting evidence to make and revise recommendations regarding vaccination to improve the safety of residents and staff while balancing the burden to facilities to report. For example, early in the PHE, increasing staff vaccination rates was associated with lower incidence of COVID–19 cases and deaths among residents and staff in LTC facilities. However, as newer, more infectious, and transmissible variants of the virus emerged, increasing staff vaccination rates of the original 2-dose regimen of the COVID–19 vaccine as recommended in December 2020, was no longer associated with lower rates of adverse COVID–19 outcomes in nursing homes, resulting in updated recommendations to the public.[144]

6. Proposed Continuation of Respiratory Illness Reporting for LTC Facilities

Given the value of respiratory illness and vaccination reporting during the COVID–19 PHE in supporting resident health and safety, we are considering the continued utility of LTC facility respiratory illness data to monitor and protect residents against respiratory illnesses and the ongoing need for such data in the ''new normal'' of diverse respiratory disease threats. While the COVID–19 PHE has ended, SARS–CoV–2 continues to circulate throughout the globe and although epidemic waves are less severe than those of 2020 through early 2022, there was no epidemiologic bright line associated with the end of the PHE. While COVID–19 hospital admissions were modestly lower in January 2024 than they were at the July 2022 or December 2022 peaks,[145] adults 65 years and older represented more than half of COVID–19 hospitalizations during October 2023 to December 2023.[146] Additionally, during the 2023–2024 fall/winter respiratory virus season, COVID–19-associated hospitalizations among LTC facility residents peaked at a weekly rate that was more than eight times higher than the peak weekly rate among all U.S. adults aged ≥70 years.[147] At the same time, other respiratory viruses have also seen a resurgence, and the moderate COVID–19 burden coinciding with resurgent influenza and RSV has led to an overall hospitalization burden larger than observed during severe influenza and RSV seasons prior to the COVID–19 pandemic.[148]

The elevated risks of respiratory viruses in the post-PHE era present ongoing threats, both direct and indirect, to resident health and safety. The result of this ''new normal'' will be more burdensome respiratory virus seasons for the foreseeable future, which promises to threaten the health and safety of LTC facility residents across the Nation.[149] In response to this changed landscape, public health agencies, such as the CDC, have shifted prevention and control strategies from a focus on specific viruses to an approach that addresses the threats presented by the broader respiratory virus season, including focused efforts to mitigate impacts on nursing home residents and staff.[150] Likewise, we believe it is vital

[141] *https://doi.org/10.1111/jgs.18402.*

[142] Haanschoten E, Dubendris H, Reses HE, Barbre K, Meng L, Benin A, Bell JM. Disparities in COVID–19 Vaccination Status Among Long-Term Care Facility Residents—United States, October 31, 2022–May 7, 2023. MMWR Morb Mortal Wkly Rep. 2023 Oct 6;72(40):1095–1098. doi: 10.15585/mmwr.mm7240a4. PMID: 37796756; PMCID: PMC10564329.

[143] Wong E, Barbre K, Wiegand RE, Reses HE, Dubendris H, Wallace M, Dollard P, Edwards J, Soe M, Meng L, Benin A, Bell JM. Effectiveness of Up-to-Date COVID–19 Vaccination in Preventing SARS–CoV–2 Infection Among Nursing Home Residents—United States, November 20, 2022–January 8, 2023. MMWR Morb Mortal Wkly Rep. 2023 Jun 23;72(25):690–693. doi: 10.15585/mmwr.mm7225a4. PMID: 37347711; PMCID: PMC10328477.

[144] Sinha S, Konetzka RT. Association of COVID–19 Vaccination Rates of Staff and COVID–19 Illness and Death Among Residents and Staff in US Nursing Homes. JAMA Netw Open. 2022;5(12):e2249002. doi:10.1001/jamanetworkopen.2022.49002.

[145] *https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00.*

[146] CDC COVID Data Tracker: Hospital Admissions (*https://covid.cdc.gov/covid-data-tracker/#datatracker-home*).

[147] Franklin D, Barbre K, Rowe TA, Reses HE, Massey J, Meng L, Dollard P, Dubendris H, Stillions M, Robinson L, Clerville JW, Jacobs Slifka K, Benin A, Bell JM. COVID–19 vaccination coverage and rates of SARS–CoV–2 infection and COVID–19-associated hospitalization among residents in nursing homes. MMWR Morb Mortal Wkly Rep 2024;73:339–344. DOI: *http://dx.doi.org/10.15585/mmwr.mm7315a3.*

[148] Respiratory Disease Season Outlook (*cdc.gov*) (*https://www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html*).

[149] Respiratory Disease Season Outlook (*cdc.gov*) (*https://www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html*).

[150] See *https://www.cdc.gov/respiratory-viruses/index.html* and data summaries of respiratory virus burden at *https://www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html* and

to maintain national surveillance of these emerging and evolving respiratory illnesses as a means of guiding infection control interventions to keep residents safe. As such, we propose to continue some of the reporting requirements finalized in November 2021 and set to expire in December 2024. Specifically, we propose to revise the infection prevention and control requirements for LTC facilities to extend reporting in NHSN for a limited subset of the current COVID–19 elements and also require reporting for data related to influenza and RSV.

Specifically, we propose to replace the existing reporting requirements for LTC facilities at § 483.80(g)(1)(i) through (ix) and (g)(2) with new requirements to report information addressing respiratory illnesses. Beginning on January 1, 2025, facilities would be required to electronically report information about COVID–19, influenza, and RSV in a standardized format and frequency specified by the Secretary. Currently, we propose to continue weekly reporting through the CDC's NHSN. To the extent to be determined by the Secretary, through this rulemaking cycle, we propose that the data elements for which reporting would be required include all of the following:

- Facility census (defined as the total number of residents occupying a bed at this facility for at least 24 hours during the week of data collection).
- Resident vaccination status for a limited set of respiratory illnesses including but not limited to COVID–19, influenza, and RSV.
- Confirmed, resident cases of a limited set of respiratory illnesses including but not limited to COVID–19, influenza, and RSV (overall and by vaccination status).
- Hospitalized residents with confirmed cases of a limited set of respiratory illnesses including but not limited to COVID–19, influenza, and RSV (overall and by vaccination status).

These proposals are scaled back and tailored from the current post-COVID–19 PHE requirements, continuing the collection of the minimal necessary data to maintain a level of situational awareness that would protect resident health and safety in LTC facilities across the country while reducing reporting burden on those facilities. We are also interested in the utility of additional reporting on limited demographic data and solicit public comment on whether the collection of data regarding race, ethnicity, and socioeconomic status should be explicitly included as part of these proposed requirements for ongoing reporting beginning on January 1, 2025. We are particularly interested in comments that address the ways these additional data elements could be used to better protect resident and community health and safety both during and outside of a declared PHE. In addition, we are interested in comments on how to protect resident privacy within demographic groups and how to best use the data to inform public health efforts without stigmatizing demographic groups.[151] Lastly, we welcome comments that address system readiness and capacity to collect and report these data.

In determining the data elements to propose for ongoing reporting, we considered the data elements that proved most actionable and informative over the course of the COVID–19 PHE, with evidence of protecting health and safety, as well as more recent lessons that have emerged during the 2023–2024 respiratory virus response.[152] [153] We also considered ways to balance the burden of reporting on LTC facilities with the need to maintain a level of situational awareness that will benefit residents, their families, and their communities.

In the absence of a declared national PHE for an acute respiratory illness, we propose that LTC facilities would continue to report these data on a weekly basis through a format specified by the Secretary with continued reporting through the CDC's NHSN. Sustained data collection and reporting outside of emergencies would help ensure that LTC facilities maintain a functional reporting capacity that could be mobilized quickly when a new threat emerges to inform and direct response efforts (for example, resource allocations) that protect residents and their communities. These data collections would also provide the baseline information necessary to forecast, detect, quantify and, ultimately, direct responses to signals of strain within regions and LTC facilities.

Unlike the previous and sunsetting LTC reporting requirements, the requirements proposed in this rule are not tied to a specific PHE declaration. PHE declarations are valuable tools for marshalling nimble and fast emergency responses. However, there are many respiratory disease threats to LTC facility operations and resident safety that would not necessarily be subject to a PHE declaration nor have significant potential to become a PHE. In those instances, routine data about cases and hospitalizations due to respiratory viruses like COVID–19, influenza, and RSV are critical to inform technical assistance, infection prevention and control support, and resource allocations to support LTC facilities and safeguard their residents.

We welcome public comments on our proposals, and on ways that reporting burden can be minimized while still providing adequate data. We also welcome feedback on any challenges of collecting and reporting these data; ways that CMS could reduce reporting burden for facilities; and alternative reporting mechanisms or quality reporting programs through which CMS could instead effectively and sustainably incentivize reporting. Finally, we welcome comments on the value of these data in protecting the health and safety of individuals receiving care and treatment and working in LTC facilities.

7. Proposed Collection of Additional Data Elements During a PHE

The COVID–19 PHE strained the healthcare system substantially, introducing new safety risks and negatively impacting patient and resident safety in the normal delivery of care. Data from the pandemic showed that the incidence of healthcare-associated infections would increase when COVID–19 hospitalizations were high,[154] a feedback loop between increased stress on hospitals, LTC facilities, illness in the community, and patient and resident health and safety.

https://www.cdc.gov/respiratory-viruses/whats-new/track-hospital-capacity.html.

[151] Landers S, Kapadia F, Tarantola D. Monkeypox, After HIV/AIDS and COVID–19: Suggestions for Collective Action and a Public Health of Consequence, November 2022. Am J Public Health. 2022 Nov;112(11):1564–1566. doi: 10.2105/AJPH.2022.307100. PMID: 36223580; PMCID: PMC9558195. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9558195/.*

[152] *https://emergency.cdc.gov/han/2023/han00503.asp, https://emergency.cdc.gov/han/2023/han00498.asp.*

[153] Coverage with Influenza, Respiratory Syncytial Virus, and Updated COVID–19 Vaccines Among Nursing Home Residents—National Healthcare Safety Network, United States, December 2023 | MMWR (*cdc.gov*) (*https://www.cdc.gov/mmwr/volumes/72/wr/mm7251a3.htm#F1_down*).

[154] Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID–19) pandemic | Infection Control & Hospital Epidemiology | Cambridge Core; *https://www.nejm.org/doi/full/10.1056/NEJMp2118285;* The impact of coronavirus disease 2019 (COVID–19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network—PubMed (*nih.gov*) (*https://pubmed.ncbi.nlm.nih.gov/34473013/*); Impact of COVID–19 pandemic on central-line-associated bloodstream infections during the early months of 2020, National Healthcare Safety Network—PubMed (*nih.gov*) (*https://pubmed.ncbi.nlm.nih.gov/33719981/*).

Degradation in other measures of resident safety, including pressure ulcers and falls, further demonstrate how the strains associated with surge response adversely affect routine safety practices.[155] [156] Specifically in LTC facilities, the significant adverse health impacts on residents caused by COVID–19 went far beyond the direct effects of COVID–19 morbidity and mortality.[157] Given the unprecedented impacts of, and learnings derived from, the COVID–19 PHE, we believe that it is imperative to enhance preparedness and resiliency to improve health system responses to future threats, including pandemics that pose catastrophic risks to resident safety. As such, we propose additional data reporting that would be required in the event of an acute respiratory illness PHE, or after the Secretary's determination that a significant threat of one exists.

Accordingly, we propose that during a declared national, State, or local PHE for a respiratory infectious disease (or if the Secretary determines a significant threat for one exists) the Secretary may require facilities to report:

- Data up to a daily frequency without additional notice and comment rulemaking.
- Additional or modified data elements relevant to the PHE, including relevant confirmed infections among staff, supply inventory shortages, staffing shortages, and relevant medical countermeasures and therapeutic inventories, usage, or both.
- If the Secretary determines that an event is significantly likely to become a PHE for an infectious disease, the Secretary may require LTC facilities to report additional or modified data elements without notice and comment rulemaking.

We invite comments on if, during a PHE, there should be limits to the data the Secretary can require without notice and comment rulemaking, such as limits on the duration of additional reporting or the scope of the jurisdiction of reporting (that is, State or local PHEs). We also seek comments on whether and how the Secretary should still seek stakeholder feedback on additional elements during a PHE without notice and comment rulemaking and how HHS should notify LTC facilities of new required infectious disease data. Furthermore, we invite comments on the evidence HHS should provide to demonstrate that—(1) an event is ''significantly likely to become a PHE''; or (2) the increased scope of required data will be used to protect resident and community health and safety. We also invite comments on the utility and burden of specifically staffing and supply shortage data we propose to collect during national, State, or local PHE for a respiratory infectious disease (or if the Secretary determines a significant threat for one exists). Based on LTC facilities experience with the COVID–19 PHE, how could HHS collect this data specifically in a way that would be beneficial to LTC facilities?

8. Collaboration

To further reduce burden in the short term, we are working with the CDC to ensure LTC facilities can continue to use existing, established systems to report data in the interim. CDC will continue increasing the automation capabilities of the surveillance systems like NHSN and its ability to connect with other data submission techniques, vendors, and systems.[158] CDC is collaborating with LTC partner organizations and State health departments to pilot projects aimed at streamlining and modernizing vaccination data reporting. This includes efforts to automate reporting of LTC facility vaccination data from electronic health records to NHSN and to connect person-level vaccination data in NHSN to State Immunization Information Systems (IIS). These modernization efforts should reduce the reporting burden on facilities over time. In addition, CDC provides users with technical assistance, targeted data quality outreach and webinars, and continues to actively collaborate with users and partners to improve system design and functionality. For example, the development of the NHSN person-level vaccination forms allowed for complex definitions that change over time (for example, up to date with COVID–19 vaccines) to be applied automatically to and aggregate resident-level data.

CMS, CDC, and the Administration for Strategic Preparedness and Response (ASPR) recognize the immense value of partnerships with LTC facilities, State, Tribal, Local, and Territorial (STLT) health systems, associations, and other partners. Throughout the COVID–19 PHE, partners at all levels worked alongside CMS, CDC, and ASPR to provide additional context, insight, and feedback based on conditions on the ground. This context helped data collections be more effective and helped provide a fuller picture than data alone. CMS, CDC, and ASPR are grateful for the many collaborations with partners on data and beyond. CDC, ASPR, and the Office of the National Coordinator for Health Information Technology (ONC) will explore opportunities to codify continued partnerships to prepare for and respond to incidents such as respiratory illnesses more effectively. We welcome public comment on ways that all public agencies involved in these types of data collections can be good partners.

VII. Provider Enrollment—Provisional Period of Enhanced Oversight

A. Background

1. Overview of Medicare Provider Enrollment

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into 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 all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 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.

As outlined in § 424.510, one such requirement is that the provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, 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 (System of Records notice (SORN): 09–70–0532, PECOS), collects important information about the provider or supplier. Such data includes, but is not limited to, general identifying

[155] Falls Risk in Long-Term Care Residents With Cognitive Impairment: Effects of COVID–19 Pandemic—PubMed (*nih.gov*) (*https://pubmed.ncbi.nlm.nih.gov/38104633/*).

[156] *https://www.nejm.org/doi/full/10.1056/NEJMp2118285.*

[157] The Adverse Effects of the COVID–19 Pandemic on Nursing Home Resident Well-Being—PMC (*nih.gov*) (*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7980137/*).

[158] For more information about USCDI+ *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

information (for example, legal business name), licensure and/or certification data, ownership information, and practice locations. The application is used for a variety of provider enrollment transactions, including the following:

- Initial enrollment—The provider or supplier is—(1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.
- Change of ownership—The provider or supplier is reporting a change in its ownership.
- Revalidation—The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515. (Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.)
- Reactivation—The provider or supplier is seeking to reactivate its Medicare enrollment and billing privileges after it was deactivated in accordance with § 424.540.
- Change of information—The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's or supplier's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines 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 previously discussed, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take 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 with this, and as we discuss in section VIII.B. of this proposed rule, we are proposing a change to our existing Medicare provider enrollment regulations.

2. Legal Authorities

There are two principal categories of legal authorities for our proposed Medicare provider enrollment provisions:

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

B. Proposed Provisions—Provisional Period of Enhanced Oversight (PPEO)

1. Background

Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. (Per section 1866(j)(3)(A) of the Act, such oversight can include, but is not limited to, prepayment review and payment caps.) As authorized by section 1866(j)(3)(B) of the Act, we previously implemented such procedures through subregulatory guidance with respect to newly enrolling HHAs' requests for anticipated payments (RAP).[159] More recently, in July 2023 we began placing new hospices located in Arizona, California, Nevada, and Texas in a provisional period of enhanced oversight. (See *https://www.cms.gov/files/document/mln7867599-period-enhanced-oversight-new-hospices-arizona-california-nevada-texas.pdf* for more information.)

During the PPEO involving HHA RAPs, CMS received several stakeholder requests for clarification regarding the PPEO's scope. One of these concerned the meaning of the term ''new'' for purposes of applying a PPEO. While section 1866(j)(3)(B) of the Act states that we may implement procedures by program instruction, we finalized new § 424.527(a) in the CY 2024 HH PPS final rule to address this issue. Specifically, new § 424.527(a)(1) through (3) defined a ''new'' provider or supplier (again, exclusively for purposes of our PPEO authority under section 1866(j)(3) of the Act) as any of the following:

- A newly enrolling Medicare provider or supplier. (This includes providers that must enroll as a new provider per the change in majority ownership provisions in § 424.550(b).)
- A certified provider or certified supplier undergoing a change of ownership consistent with the principles of 42 CFR 489.18. (This includes providers that qualify under § 424.550(b)(2) for an exception from the change in majority ownership requirements in § 424.550(b)(1) but which are undergoing a change of ownership under 42 CFR 489.18.)
- A provider or supplier (including an HHA or hospice) undergoing a 100 percent change of ownership via a change of information request under § 424.516.

We included these transactions within this definition because they have historically involved the effective establishment of a new provider or supplier for purposes of Medicare enrollment. For this reason, we have also received recent inquiries as to whether a reactivation should fall within the scope of § 424.527(a).

Under § 424.540 and the definition of ''deactivate'' in § 424.502, a deactivated provider's or supplier's enrollment and billing privileges are ''stopped but can be restored upon the submission of updated information.'' This restoration, or reactivation, generally involves: (1) the completion of a full Form CMS–855 application; and (2) a CMS or MAC determination as to whether the provider or supplier meets all enrollment requirements. These two steps generally mirror what occurs with the initial and change of ownership applications referenced in § 424.527(a). Although a deactivation does not rise to the level of a revocation of Medicare enrollment and billing privileges under § 424.535—for a revocation bars the provider or supplier from reenrolling in Medicare for a period of 1 to 10 years (with certain exceptions)—a deactivated provider or supplier cannot resume billing Medicare until the requirements for reactivation are met. It has, in effect, been blocked from the Medicare program. Indeed, as with a provider or supplier that voluntarily terminated its Medicare enrollment and now seeks to rejoin the program via an initial, new enrollment application, a reactivating provider, too, is requesting to rejoin the program. Described otherwise, a reactivating provider or supplier is resuming its involvement in the Medicare program after a stoppage (which, at least for practical and operational purposes, amounts to a loss) of Medicare enrollment and billing privileges. From this standpoint, we thus believe that a reactivating provider or supplier is no less ''new'' (for provider enrollment purposes) than one that is initially enrolling or undergoing a change of ownership.

Our interpretation is also supported by the fact that a significant number of our grounds for deactivation under

[159] CMS eliminated the use of RAPs for HHAs; beginning January 1, 2022, CMS replaced RAP submissions with a Notice of Admission.

§ 424.540(a) involve conduct or inaction in which the provider or supplier—as with a revocation—is not adhering to Medicare enrollment requirements. These include, for example, the provider or supplier—

- Failing to report a change to the information supplied on the enrollment application within the required timeframe (§ 424.540(a)(2));
- Failing to timely respond to a revalidation request (§ 424.540(a)(3));
- Failing to maintain compliance with all enrollment requirements (§ 424.540(a)(4)); and
- Having a non-operational or otherwise invalid practice location (§ 424.540(a)(5)).

The provider or supplier can also be revoked under § 424.535(a) on any of these bases (for instance, under § 424.535(a)(1) relating to noncompliance). Because these bases are overlapping, it is CMS' principled view that reactivating providers and suppliers that were deactivated for any of these reasons should be subject to the same PPEO scrutiny. CMS has a legitimate oversight interest that the prior non-compliance has been corrected and that adherence will continue after their reactivation, which would be satisfied through the post-enrollment monitoring the PPEO affords.

Concerning our other deactivation grounds, § 424.540(a)(1) permits CMS to deactivate a provider or supplier that has not billed Medicare for 6 consecutive months. We recognize that there may be a legitimate reason for which a provider or supplier ceases billing Medicare for an extended period. (For example, a provider enrolls in Medicare strictly to enroll in and bill another health care program.) At the same time, a reactivation request after months of billing inactivity raises questions as to whether—

- The provider or supplier is and will remain compliant with Medicare enrollment requirements once reactivated following such a period of non-billing;
- Another party has compromised the provider's or supplier's deactivated enrollment and billing privileges and seeks to fraudulently bill Medicare via the latter's reactivated enrollment; or
- The provider or supplier had secured multiple billing numbers, one of which was revoked for improper activity, another was deactivated for non-billing, and the provider or supplier now seeks to reactivate the latter number to bill for services that were previously furnished under the revoked number.

CMS has indeed identified such scenarios in its program integrity oversight activities. We believe that using a PPEO to closely monitor reactivated providers or suppliers that had been deactivated under § 424.540(a)(1) would help prevent improper activity and help ensure program integrity where the PPEO applies.

Deactivation can also occur under § 424.540 if: (1) the provider or supplier is voluntarily withdrawing from the Medicare program (that is, voluntarily terminating its Medicare enrollment) (§ 424.540(a)(7)); (2) the provider is the seller (and is hence leaving the Medicare program) in an HHA change in majority ownership under § 424.550(b) (§ 424.540(a)(8)); or (3) an individual provider or supplier is deceased (§ 424.540(a)(6)). The same concerns we expressed regarding reactivations following a § 424.540(a)(1) deactivation apply to these three deactivation bases. If a reactivation request arrives after the provider or supplier was deactivated upon departing the Medicare program, the provider's or supplier's former enrollment may have been compromised by an unscrupulous party. Even if no improper conduct is involved and the voluntarily terminated provider or supplier simply wishes to reenter and resume billing Medicare, they are effectively returning to the program as a new provider or supplier after having departed. This situation is not appreciably different from that where the provider or supplier is enrolling in Medicare for the first time. Given this, we believe that providers and suppliers that are reactivating their enrollment after having left the Medicare program should be subject to the same PPEO analysis as other providers and suppliers who are treated as an initial enrollee for Medicare provider enrollment purposes, for consistency and uniformity.

For all the foregoing reasons, we propose to add a new paragraph (a)(4) to § 424.527 that includes providers and suppliers that are reactivating their enrollment and billing privileges under § 424.540(b). We have elected to address this issue via rulemaking in proposed § 424.527(a)(4). However, we retain the authority under section 1866(j)(3)(B) of the Act to establish and implement PPEO procedures via subregulatory guidance.

VIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide a 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.

B. Information Collection Requirements (ICRs)

In the CY 2024 HH PPS rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

1. ICRs for HH QRP

As discussed in section III.D.3. of this proposed rule, we are proposing to collect four additional items as standardized patient assessment data elements and replace one item collected as a standardized patient assessment data element beginning with the CY 2027 HH QRP. The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities. We also propose replacing the current Access to Transportation item with a revised Transportation (Access to Transportation) item beginning with the CY 2027 HH QRP as outlined in section III.D.5. of this proposed rule. All elements discussed will be collected at the start of care timepoint. We assumed the Living Situation and Utilities data elements require 0.3 minutes each of clinician time to complete. We assume the Food Runs Out and Food Doesn't Last data elements require 0.15 minutes each of clinician time to complete. We assume the replacement of the current Access to Transportation item with a revised Transportation will not result in a change in burden. Therefore, we estimated that there will be an increase

in clinician burden per OASIS assessment of 0.9 minutes at start of care.

As stated in section III.E. of this proposed rule, CMS is also proposing an update to the removal of the suspension of OASIS all-payer data collection to change all-payer data collection beginning with the start of care OASIS data collection timepoint instead of discharge timepoint. There is no associated change in burden resulting from this proposal as burden for collection of for non-Medicare/non-Medicaid patients at all OASIS data collection timepoints was estimated in the CY 2023 HH PPS final rule.

The net effect of these proposals is an increase in four data elements collected at the start of care for the OASIS implemented on January 1, 2027.

For purposes of calculating the costs associated with the information collection requirements, we obtained median hourly wages for these from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). To account for other indirect costs such as overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in table 41.

TABLE 41: U.S. BUREAU OF LABOR STATISTICS' MAY 2023 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$41.38	$41.38	$82.76
Physical therapists (PT)	29-1123	$47.94	$47.94	$95.88
Speech-Language Pathologists (SLP)	29-1127	$42.93	$42.93	$85.86
Occupational Therapists (OT)	29-1122	$46.33	$46.33	$92.66
Miscellaneous Health Technologists and Technicians	29-2090	$29.05	$29.05	$58.10

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2021 show that the SOC/ROC OASIS is completed by RNs (approximately 77.14 percent of the time), PTs (approximately 22.16 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.7 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of $85.73, inclusive of fringe benefits, using the hourly wage data in table 41 $0.7714 \times 82.76 + 0.2216 \times 95.98 + 0.007 \times 89.26 = 85.74$. Individual providers determine the staffing resources necessary.

For purposes of estimating burden, we compare the item-level burden estimates for the OASIS that will be released on January 1, 2027, to the OASIS–E1 as anticipated for implementation as of January 1, 2025, and finalized in CY2024 HH PPS Final Rule. The first component needed to calculate burden is the total estimated assessments for each year in question. Table 42 shows the total number of OASIS assessments that HHAs completed in CY 2023 at start of care and resumption of care. It also outlines the estimated assessments that are expected to be collected in 2025 based on a thirty percent increase in completed assessments required for all payer data submission requirements for (CY23 assessment total + CY23 assessment total *0.3 = Estimated CY25 Assessment total based on all payer data collection).

TABLE 42. START OF CARE/RESUMPTION OF CARE OASIS SUBMISSIONS BASED ON CY 2023 & CY 2025 ESTIMATED OASIS DATA

Time Point	CY 2023 OASIS Assessments Completed	Estimated CY 2025 OASIS Assessments Based on All-Payer Data Collection
Start of Care	6,627,912	8,616,286
Resumption of Care	911,245	1,184,618
Total Assessments	7,539,157	9,800,904

The totals from table 42 are used to calculate the hourly burden estimates in table B3 based on the following calculations:

Start of Care

Estimated time spent per each 2025 OASIS–E1 SOC Assessment/Patient = 56.4 clinician minutes

200 data elements × (range of 0.15 to 0.3) minutes per data element = 56.4 minutes of clinical time spent to complete data entry for the OASIS–E1 SOC assessment.

- 21 data elements counted as 0.15 minutes/data element (3.15 minutes)
- 9 data elements counted as 0.25 minutes/data element (2.25 minutes)
- 170 data elements counted as 0.30 minutes/data element (51 minutes)

Clinician Estimated hourly burden for all HHAs (11,904) for 2025 OASIS–E1 SOC assessments = 8,099,309 hours

56.4 clinician minutes per SOC assessment × 8,616,286 assessments = 485,958,530 minutes/60 minutes per hour = 8,099,309 hours for all HHAs

Estimated time spent per each 2027 OASIS SOC Assessment/Patient = 57.3 clinician minutes

204 data elements × (range of 0.15 to 0.3) minutes per data element = 57.3 minutes of clinical time spent to complete data entry for the OASIS SOC assessment.

- 23 data elements counted as 0.15 minutes/data element (3.45 minutes)
- 9 data elements counted as 0.25 minutes/data element (2.25 minutes)
- 172 data elements counted as 0.30 minutes/data element (51.6 minutes)

Clinician Estimated hourly burden for all HHAs (11,904) for 2027 OASIS SOC assessments = 8,228,553 hours

57.3 clinician minutes per SOC assessment × 8,616,286 assessments = 493,713,188 = minutes/60 minutes per hour = 8,228,553 hours for all HHAs

Resumption of Care

Estimated time spent per each 2025 OASIS–E1 ROC Assessment/Patient = 47.1 minutes

169 data elements × (range of 0.15 to 0.3) minutes per data element = 47.1 minutes of clinical time spent to complete data entry for the OASIS–E1 ROC assessment

- 19 data elements counted as 0.15 minute/data element (2.85 minutes)
- 9 data elements counted as 0.25 minute/data element (2.25 minutes)
- 140 data elements counted as 0.30 minute/data element (42 minutes)

Clinician Estimated Hourly Burden for all HHAs for 2025 OASIS–E1 ROC assessments = 823,310 hours

47.1 clinician minutes per ROC assessment × 1,184,618 ROC assessments = 55,795,508 minutes/60 minutes = 929,925hours for all HHAs

Estimated time spent per each 2027 OASIS ROC Assessment/Patient = 48 minutes

173 data elements × (range of 0.15 to 0.3) minutes per data element = 48 minutes of clinical time spent to complete data entry for the OASIS ROC assessment

- 21 data elements counted as 0.15 minute/data element (3.15 minutes)
- 9 data elements counted as 0.25 minute/data element (2.25 minutes)
- 142 data elements counted as 0.30 minute/data element (42.6 minutes)

Clinician Estimated Hourly Burden for all HHAs for 2027 OASIS ROC assessments = 947,694 hours

48 clinician minutes per ROC assessment × 1,184,618 ROC assessments = 56,861,664 minutes/60 minutes = 947,694 hours for all HHAs

Table 43 summarizes the estimated clinician hourly burden for the OASIS that will be implemented in 2027 with this proposed rule's changes of an increase in four data elements at start of care and resumption of care compared to the anticipated 2025 OASIS–E1 burden. This is calculated by multiplying the total number of assessments by the increase in assessment time required. We calculate the 2025 and 2027 burden estimate in minutes and then calculate an hourly burden shown in table 43. We estimated a net increase of 147,013 hours of clinician burden across all HHAs or 12.35 hours (147,013/11,904) for each of the 11,904 active HHAs.

TABLE 43. SUMMARY OF ESTIMATED CLINICIAN HOURLY BURDEN FOR CY 2025 AND CY 2027

OASIS Assessment Type	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2025	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2027	Total Increase in Hours
Start of Care	8,099,309	8,228,553	+129,244
Resumption of Care	929,925	947,694	+17,769
Totals	9,029,234	9,176,247	+147,013

Table 44 summarizes the estimated clinician costs for the 2025 OASIS–E1 and the 2027 OASIS with the net addition of four data elements at start of care using CY 2023 BLS wage inputs. Total clinician cost for 2025 and 2027 is estimated by multiplying total hourly burden for each year as reported in table 43 by the weighted clinician average hourly wage of $85.74. We then calculate the difference in clinician estimated costs between 2027 and 2025. This calculates the estimated increase in costs associated with adding the four data elements at start of care and resumption of care. We estimate an increase in clinician costs $12,604,894.62 between 2027 and 2025 related to the implementation of the proposals outlined in this proposed rule across all HHAs or a $1,058.88 increase (12,604,894.62/11,904) for each of the 11,904 active HHAs. This increase in burden will begin with the January 1, 2027, OASIS assessments.

TABLE 44. SUMMARY OF ESTIMATED CLINICIAN COSTS FOR CY 2025 AND CY 2027

OASIS Assessment Type	Clinician Estimated Cost – OASIS-E1 2025	Clinician Estimated Cost – OASIS 2027	Total Cost Increase
Start of Care	$ 694,434,753.66	$ 705,516,134.22	+$11,081,380.56
Resumption of Care	$ 79,731,769.50	$ 81,255,283.56	+$1,523,514.06
Totals	$ 774,166,523.16	$ 786,771,417.78	+$12,604,894.62

2. ICRs for the Expanded HHVBP Model

The RFI and the health equity update for the expanded HHVBP Model included in section IV. of this proposed rule do not result in an increase in costs to HHAs. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the expanded HHVBP Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

3. ICRs Related to Conditions of Participation (CoPs): Organization and Administration of Services (§ 484.105)

In section VII.A. of this proposed rule, we discuss our proposal to add a new standard at § 484.105(i), which would set forth a requirement for HHAs to establish an ''acceptance to service'' policy. This new standard would require the HHA to develop, implement, and maintain through an annual review a patient acceptance to service policy that addressed criteria related to the HHA's capacity to provide patient care, including, but not limited to, anticipated needs of the referred prospective patient, case load and case mix of the HHA, staffing levels of the HHA, and competencies and skills of the HHA staff. In addition, we propose the HHA would have to make public accurate information about the services offered by the HHA and any limitations related to the types of specialty services, service duration, and service frequency. We believe that most HHAs already have a policy related to the admission to service. The burden associated with this requirement is the burden required to develop, implement, and maintain an updated policy that would meet the requirements of this proposed rule, and the burden associated with making specified information available to the public.

Section 1861(o)(2) of the Act requires HHAs to have policies established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses. Therefore, we expect the HHA to utilize a physician and nurse to create and update the HHA's policies. We estimate there are 9,565 Medicare-certified HHAs and that this proposed new requirement would take 1 hour each of a physician and a registered nurse's time on a one-time basis, for an HHA to develop an acceptance to service policy at a cost of $321.84 per HHA ($82.76 + $239.08) and $3,078,400 for all HHA's ($791,599 + $2,286,800). We also estimate the HHA nurse would review the acceptance to service policy on an annual basis. This annual review would take 5 minutes for an HHA nurse at a cost of $7 per HHA ($82.76 × 5/60 minute = $6.90) or $65,999 for all HHAs ($6.90 × 9,565 = $65,999) to fulfill this requirement.

TABLE 45: U.S. BUREAU OF LABOR STATISTICS' MAY 2023 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN) https://www.bls.gov/oes/current/oes291141.htm	29-1141	$41.38	$41.38	$82.76
Physician https://www.bls.gov/oes/current/oes291229.htm	29-1229	$119.54	$119.54	$239.08
Medical Administrative Assistant https://www.bls.gov/oes/current/oes436013.htm	46-6013	$20.85	$20.85	$41.70

TABLE 46: SUMMARY OF ESTIMATED COSTS FOR THE ACCEPTANCE TO SERVICE POLICY

Estimated Burden § 484.105: Acceptance to Service Policy	Total Number of HHA's	Net Total
82.76	9,565	$791,599
$239.08	9,565	$2,286,800
$321,84(one time cost)	9,565	$3,078,400
$6.90 (annually)	9,565	$65,999
$10.43 (one time cost)	9,565	$99,763
$3.48 (annually)	9,565	$33,286

In addition, we estimate this proposed new requirement would take 15 minutes on a one-time basis for an HHA to the specified information public at a cost of $10.43 per HHA or $99,763 for all HHA's, based on the assumption that the HHA administrative professional will process this task. The average hourly rate for an administrative employee is $41.70, therefore it is $10.43 per HHA ($41.70 hour × 15/60 minutes = $10.43) or $99,763 for all HHA's ($10.43 × 9,565) to fulfill the requirement. We also estimate the HHA administrative professional would review this website annually to assure the continued accuracy of the posted information. This annual review would take 5 minutes at a cost of $3.48 per HHA ($41.70 × 5/60 minute = $3.48) or $33,286 for all HHA's (3.48 × 9,565 = $33,286) to fulfill this requirement.

Administrative professional: *https://www.bls.gov/oes/current/oes436013.htm.*

4. ICRs for Provider Enrollment Provisions

Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and

suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. These procedures have been codified in § 424.527. As explained in section VII. of this proposed rule, we are proposing to expand the definition of ''new provider or supplier'' in § 424.527(a) (solely for purposes of applying a provisional period of enhanced oversight (PPEO)) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges under § 424.540(b). We do not anticipate any ICR burdens associated with this provision, for we are merely expanding an existing regulatory definition.

5. ICRs Related to LTC Requirements for Acute Respiratory Illness Reporting § 483.80(g)

The ICR burden currently associated with § 483.80(g) is included under OMB control number 0938–1363; expiration date: April 30, 2026.

In section VII.B. of this proposed rule we discuss our proposals related to LTC requirements for acute respiratory illness reporting. At § 483.80(g)(1)(i) through (ix) and (g)(2), we propose to replace the existing reporting requirements for LTC facilities with new requirements to report information addressing respiratory illnesses. Beginning on January 1, 2025, facilities would be required to electronically report information about COVID–19, influenza, and RSV in a standardized format and frequency specified by the Secretary. To the extent to be determined by the Secretary, through this rulemaking cycle, we propose that the data elements for which reporting would be required include—

- Facility census;
- Resident vaccination status for a limited set of respiratory illnesses including but not limited to COVID–19, influenza, and RSV;
- Confirmed, resident cases of a limited set of respiratory illnesses including but not limited to COVID–19, influenza, and RSV (overall and by vaccination status); and
- Hospitalized residents with confirmed cases of a limited set of respiratory illnesses including but not limited to COVID–19, influenza, and RSV (overall and by vaccination status.).

In the absence of a declared national PHE for an acute respiratory illness, we propose that LTC facilities would continue to report these data on a weekly basis through a format specified by the Secretary and specifically we intend to continue reporting through the CDC's NHSN. There may be instances in which the Secretary may determine a need to change reporting frequency, such as during a future PHE, and we would provide appropriate notice and guidance at that time.

These proposals are scaled back and tailored from the current post-COVID–19 PHE requirements, continuing the collection of the minimal necessary data to maintain a level of situational awareness that would protect resident health and safety in LTC facilities across the country while reducing reporting burden on those facilities. However, during a declared Federal, state, or local PHE for a respiratory infectious disease we also propose that the Secretary may require facilities to report:

- Data up to a daily frequency without additional notice and comment rulemaking.
- Additional or modified data elements relevant to the PHE, including relevant confirmed infections among staff, supply inventory shortages, and relevant medical countermeasures and therapeutics inventories, usage, or both, and additional demographic factors.

Since the infection prevention and control program (IPCP) is the responsibility of the infection preventionist (IP), we anticipate that the IP would be responsible for reviewing and updating the policies and procedures for the facility's IPCP to comply with these new proposals. We estimate that it would require 2 hours of the IP's time to update the facility's policies and procedures to ensure that they reflect the proposed requirements. In analyzing the ICRs related to this proposal we obtained salary information from the May 2023 National Occupational Employment and Wage Estimates, BLS at *https://www.bls.gov/oes/current/oes_nat.htm.* We have calculated the estimated hourly rate for an IP using the occupation code for a registered nurse (29–1141) based on the national mean salary increased by 100 percent to account for overhead costs and fringe benefits ($45.42 × 2= $90.84 (rounded to $91). According to CMS, there are currently 14,926 LTC facilities as of April 2024.[160]

Based on this salary information and facility data, we estimate that total annual burden hours for all LTC facilities to review and update their current policies and procedures would be 29,852 hours (2 hours × 14,926 facilities) at a cost of $2,716,532 (29,852 × $91) or $182 ($91 × 2 hours) per facility annually.

In addition, LTC facilities will need to continue locating the required information and electronically reporting in the frequency specified to the NHSN. Currently, the ICR associated with this reporting requirement under OMB control #0938–1363 estimates a total burden cost of $55,972,800 (1 hour × 52 weeks × $69 (IP 2022 salary) × 15,600 LTC facilities as of 2022) based on weekly reporting. While the number of required data elements for ongoing reporting have decreased from the current post-COVID–19 PHE reporting requirements set to expire December 2024, we acknowledge that the data elements and reporting frequency could increase or decrease due to what the Secretary deems necessary based on changes in circumstance or given another PHE and these changes would impact this burden estimate. For instance, weekly data reporting could be decreased to bi-weekly reporting or the increased reporting of additional data elements during a PHE could be activated and remain active for less than or more than a year depending on the circumstances. Since we cannot predict with certainty how often the Secretary would require data reporting for a future PHE, we are including two burden estimates to cover a range in frequency of reporting. The lower range is based on weekly reporting and the higher range is based on daily reporting.

Based on the assumption of a weekly reporting frequency and 1 hour of the IP's time to locate and electronically report the information, we estimate that total annual burden hours for all LTC facilities to comply would be 776,152 hours (1 hour × 52 weeks × 14,926 facilities) at a cost of $70,629,832 (776,152 total hours × $91) or $4,732 ($91 × 1 hour × 52 weeks) per facility annually.

Based on the assumption of a daily reporting frequency, we estimate that total annual burden hours for all LTC facilities to comply would be 5,447,990 hours (1 hour × 365 days a year × 14,926 facilities) at a cost of $495,767,090 (5,447,990 total hours × $91) or $33,215 ($91 × 1 hour × 365 days a year) per facility annually.

In summary the total annual burden for all LTC facilities for these proposed ICRs is 806,004 to 5,477,842 hours at an estimated cost of $73,346,364 to $498,483,622 or 54 to 367 hours at an estimated cost of $4,914 to $33,397 per

[160] *https://qcor.cms.gov/active_nh.jsp?which=0&report=active_nh.jsp,* report ran 4/24/2024.

facility annually. We will submit the revised information collection request to OMB for approval under OMB control number 0938–1363.

TABLE 47: TOTAL BURDEN FOR § 483.80(g) ICRs

LTC Requirements Section	Number of LTC Facilities	Hourly Wage Rate	Burden Hours Per LTC Facility	Cost Estimate Per LTC Facility	Burden Hours For All LTC Facilities	Cost Estimate For All LTC Facilities
§483.80(g)(1) and (2) Policies and Procedures	14,926	$91	2	$182	29,852	$2,716,532
§483.80(g)(1) and (2) Electronically Reporting	14,926	$91	52 to 365	$4,732 to $33,215	776,152 to 5,447,990	$70,629,832 to $495,767,090
Totals	14,926	$91	54 to 367	$4,914 to $33,397	806,004 to 5,477,842	$73,346,364 to $498,483,622

We welcome public comments on our ICR burden estimates, and on ways that reporting burden can be minimized while still providing adequate data. We also welcome feedback on any challenges of collecting and reporting these data; ways that CMS could reduce reporting burden for facilities; and alternative reporting mechanisms or quality reporting programs through which CMS could instead effectively and sustainably incentivize reporting. Lastly, we welcome comments that address system readiness and capacity to collect and report these data.

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections, as previously discussed, please visit the CMS website at *https://www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements.

IX. 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 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.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by sections 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. Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, 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. 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. HH QRP

Section 1895(b)(3)(B)(v) of the Act authorizes the HH QRP, which requires

HHAs to submit data in accordance with the requirements specified by CMS. Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

3. Expanded HHVBP Model

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) and codified at 42 CFR part 484, subpart F, we finalized our policy to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. CY 2023 was the first performance year in which HHAs individual performance on the applicable measures will affect their Medicare payments in CY 2025. In this proposed rule, we include a request for information (RFI) related to the future measure concepts for the expanded HHVBP Model. We also provide an update on potential future approaches for integrating health equity that are being considered for the expanded HHVBP Model.

4. Home IVIG Items and Services

Division FF, section 4134 of the CAA, 2023 (Pub. L. 117–328) mandated that CMS establish a permanent, bundled payment for items and services related to administration of IVIG in a patient's home. The permanent, bundled home IVIG items and services payment is effective for home IVIG infusions furnished on or after January 1, 2024. Payment for these items and services is required to be a separate bundled payment made to a supplier for all items and services furnished in the home during a calendar day. This payment amount may be based on the amount established under the Demonstration. The standard Part B coinsurance and the Part B deductible apply. The separate bundled payment does not apply for individuals receiving services under the Medicare home health benefit. The CAA, 2023 provision clarifies that a supplier who furnishes these services meet the requirements of a supplier of medical equipment and supplies.

5. HHA CoP Changes: Establishing an Acceptance to Service Policy

In sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in regulations at 42 CFR part 484, Home Health Services, and regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare Conditions of Participation (CoPs). Section 1861(o)(6) of the Act requires that an HHA must meet the CoPs specified in section 1891(a) of the Act, and other CoPs as the Secretary finds necessary in the interest of the health and safety of patients. The CoPs for HHAs protect all individuals under the HHA's care, unless a requirement is specifically limited to Medicare beneficiaries. As explained in section VI.A. of this proposed rule, we are proposing to add a new standard at § 484.105(i) that would require HHAs to develop, consistently apply, and maintain an acceptance to service policy, including specified factors, that would govern the process for accepting patients to service. We also propose that HHAs would be required to make specified information about their services and service limitations available to the public. In this proposed rule, we include a request for information (RFI) to obtain information from stakeholders on whether CMS should shift its longstanding policy and permit rehabilitative therapists to conduct the initial and comprehensive assessment for cases that have both therapy and nursing services ordered as part of the plan of care. In addition, we are seeking public comments on other factors that influence the patient referral and intake processes.

6. Provider Enrollment Provisions

Section 1866(j)(3)(A) of the Act states that the Secretary shall establish procedures to provide for a provisional period of between 30 days and 1 year during which new providers and suppliers—as the Secretary determines appropriate, including categories of providers or suppliers—will be subject to enhanced oversight. These procedures have been codified in 42 CFR 424.527. As explained in section VII. of this proposed rule, we are proposing to expand the definition of ''new provider or supplier'' in § 424.527(a) (solely for purposes of applying a provisional period of enhanced oversight (PPEO) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges under § 424.540(b).

7. LTC Requirements for Acute Respiratory Illness Reporting

Sections 1819(d)(3) and 1919(d)(3) of the Act explicitly require that LTC facilities develop and maintain an infection control program that is designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public. In addition, sections 1819(d)(4)(B) and 1919(d)(4)(B) of the Act explicitly authorize the Secretary to issue any regulations he deems necessary to protect the health and safety of residents. As such, we are proposing streamlined weekly data reporting requirements for certain respiratory illnesses. We are also proposing additional, related data elements that could be activated in the event of a future acute respiratory illness PHE.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 amends section 3(f) of Executive Order 12866 to define a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for significant rules.

Based on our estimates, OMB'S Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year. Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed this proposed rule, and the Departments have provided the following assessment of their impact. We solicit comments on the regulatory impact analysis provided.

C. Detailed Economic Analysis

1. Effects of the Proposed Changes for the CY 2025 HH PPS

This rule proposes to update Medicare payments under the HH PPS for CY 2025. The net transfer impact related to the changes in payments under the HH PPS for CY 2025 is estimated to be −$280 million (−1.7 percent). The $280 million decrease in estimated payments for CY 2025 reflects the effects of the proposed CY 2025 home health payment update percentage of 2.5 percent ($415 million increase), an estimated 3.6 percent decrease that reflects the effects of the permanent adjustment ($595 million decrease), and an estimated 0.6 percent decrease that reflects the effects of an updated FDL ($100 million decrease).

We use the latest data and analysis available. However, we do not adjust 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 that ended on or before December 31, 2023. 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 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 48 represents how HHA revenues are likely to be affected by the proposed policy changes for CY 2025. For this analysis, we used an analytic file with linked CY 2023 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2023. The first column of table 48 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 permanent assumption adjustment on all payments. The aggregate impact of the permanent adjustment reflected in the third column does not equal the proposed −4.067 percent permanent adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The fourth column shows the payment effects of the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor. The fifth column shows the payment effects of updating the CY 2025 wage index (that is, the FY 2025 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021 (FY 2021 cost report data)) with the revised OMB delineations and a 5-percent cap on wage index decreases. The aggregate impact of the changes in the fifth column is zero percent, due to the wage index budget neutrality factor. The sixth column shows the payment impacts of the proposed update to the LUPA add-on factors. The seventh column shows the payment effects of the proposed CY 2025 home health payment update percentage. The eighth column shows the payment effects of the revised FDL, and the last column shows the combined effects of all the proposed provisions.

Overall, it is projected that aggregate payments in CY 2025 would decrease by 1.7 percent which reflects the 3.6 percent decrease from the permanent adjustment, the 2.5 payment update percentage increase, and the 0.6 percent decrease from increasing the FDL. As illustrated in table 48, the combined effects of all 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 2025 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 48: CY 2025 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	Permanent Adjustment	CY 2025 Case-Mix Weights Recalibration Neutrality Factor	CY 2025 Updated Wage Index (with 5% cap and OMB Delineations)	CY 2025 Proposed LUPA Add-On Factors Update	CY 2025 Proposed HH Payment Update Percentage	Fixed-Dollar Loss (FDL) Update	Total
All Agencies	**9,565**	**-3.6%**	**0.0%**	**0.0%**	**0.0%**	**2.5%**	**-0.6%**	**-1.7%**
Facility Type and Control								
Free-Standing/Other Vol/NP	865	-3.5%	0.0%	-0.5%	0.0%	2.5%	-0.7%	-2.2%
Free-Standing/Other Proprietary	7,029	-3.7%	0.0%	0.2%	0.0%	2.5%	-0.5%	-1.5%
Free-Standing/Other Government	149	-3.6%	0.0%	0.3%	0.0%	2.5%	-0.7%	-1.5%
Facility-Based Vol/NP	429	-3.4%	0.0%	-0.4%	0.0%	2.5%	-0.9%	-2.2%
Facility-Based Proprietary	44	-3.6%	0.2%	0.6%	0.0%	2.5%	-0.5%	-0.8%
Facility-Based Government	137	-3.5%	0.0%	0.3%	0.0%	2.5%	-0.7%	-1.4%
Subtotal: Freestanding	8,043	-3.6%	0.0%	0.1%	0.0%	2.5%	-0.6%	-1.6%
Subtotal: Facility-based	610	-3.4%	0.0%	-0.2%	0.0%	2.5%	-0.8%	-1.9%
Subtotal: Vol/NP	1,294	-3.5%	0.0%	-0.5%	0.0%	2.5%	-0.8%	-2.3%
Subtotal: Proprietary	7,073	-3.7%	0.0%	0.2%	0.0%	2.5%	-0.5%	-1.5%
Subtotal: Government	286	-3.5%	0.0%	0.3%	0.0%	2.5%	-0.7%	-1.4%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	205	-3.5%	0.1%	0.7%	0.0%	2.5%	-0.7%	-0.9%
Free-Standing/Other Proprietary	731	-3.7%	0.2%	1.5%	0.0%	2.5%	-0.4%	0.1%
Free-Standing/Other Government	101	-3.5%	0.2%	0.9%	0.0%	2.5%	-0.8%	-0.7%
Facility-Based Vol/NP	187	-3.4%	0.1%	0.8%	0.0%	2.5%	-0.9%	-0.9%
Facility-Based Proprietary	14	-3.8%	0.5%	-0.6%	0.0%	2.5%	-0.4%	-1.8%
Facility-Based Government	100	-3.5%	0.1%	0.4%	0.0%	2.5%	-0.9%	-1.4%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	660	-3.5%	0.0%	-0.7%	0.0%	2.5%	-0.7%	-2.4%
Free-Standing/Other Proprietary	6,290	-3.7%	0.0%	0.1%	0.0%	2.5%	-0.5%	-1.6%
Free-Standing/Other Government	48	-3.6%	-0.1%	-0.1%	0.0%	2.5%	-0.6%	-1.9%
Facility-Based Vol/NP	242	-3.4%	-0.1%	-0.6%	0.0%	2.5%	-0.9%	-2.5%
Facility-Based Proprietary	30	-3.6%	0.1%	0.9%	0.0%	2.5%	-0.6%	-0.7%
Facility-Based Government	37	-3.5%	-0.1%	0.2%	0.0%	2.5%	-0.7%	-1.6%
Facility Location: Urban or Rural								
Rural	1,338	-3.7%	0.2%	1.2%	0.0%	2.5%	-0.5%	-0.3%
Urban	7,307	-3.6%	0.0%	-0.1%	0.0%	2.5%	-0.6%	-1.8%
Facility Location: Region of the Country (Census Region)								
New England	298	-3.5%	-0.1%	-1.4%	0.0%	2.5%	-0.7%	-3.2%
Mid Atlantic	376	-3.6%	-0.1%	-1.2%	0.0%	2.5%	-0.6%	-3.0%
East North Central	1,418	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%
West North Central	567	-3.5%	0.0%	0.9%	0.0%	2.5%	-0.8%	-0.9%

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	Number of Agencies	Permanent Adjustment	CY 2025 Case-Mix Weights Recalibration Neutrality Factor	CY 2025 Updated Wage Index (with 5% cap and OMB Delineations)	CY 2025 Proposed LUPA Add-On Factors Update	CY 2025 Proposed HH Payment Update Percentage	Fixed-Dollar Loss (FDL) Update	Total
South Atlantic	1,546	-3.6%	0.0%	1.0%	0.0%	2.5%	-0.5%	-0.6%
East South Central	357	-3.7%	0.2%	2.2%	0.0%	2.5%	-0.4%	0.8%
West South Central	1,985	-3.7%	0.1%	1.3%	0.0%	2.5%	-0.6%	-0.4%
Mountain	702	-3.6%	-0.1%	1.3%	0.0%	2.5%	-0.7%	-0.6%
Pacific	2,273	-3.6%	0.0%	-1.9%	0.0%	2.5%	-0.6%	-3.6%
Outlying	43	-3.7%	0.5%	-1.2%	0.0%	2.5%	-0.5%	-2.4%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,177	-3.6%	0.1%	0.1%	0.0%	2.5%	-0.7%	-1.6%
100 to 249	1,520	-3.6%	0.0%	-0.2%	0.0%	2.5%	-0.7%	-2.0%
250 to 499	1,693	-3.6%	0.0%	-0.1%	0.0%	2.5%	-0.6%	-1.8%
500 to 999	1,891	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%
1,000 or More	2,284	-3.6%	0.0%	0.0%	0.0%	2.5%	-0.6%	-1.7%

Source: CY 2023 Medicare claims data for periods with matched OASIS records ending in CY 2023 (as of March 19, 2024).

Notes: The estimated 3.6 percent decrease related to the proposed permanent adjustment includes all payments, while the proposed -4.067 percent permanent adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The "Proposed Wage Index" column reflects updated hospital wage index data (reflecting 2021 cost report data) with the revised OMB delineations from OMB Bulletin No. 23-01 and a 5-percent cap on wage index decreases. The "Proposed LUPA Add-On Factors Update" column has an impact range of -0.01 percent to -0.035 percent which is reflected in the table as 0.0 percent due to rounding. "The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.27 to 0.38. Due to missing Provider of Services file information (from which home health agency characteristics are obtained), some subcategories in the impact tables have fewer agencies represented than the overall total (of 9,565): totals involving facility type or control only add up to 8,653 and totals involving urban/rural locations only add up to 8,645.

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. Effects of the Proposed Changes for the HH QRP for CY 2027

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. For the CY 2023 program year, 820 of the 11,549 active Medicare-certified HHAs, or approximately 7.1 percent, did not receive the full annual percentage increase because they did not meet assessment submission requirements. The 820 HHAs that did not satisfy the reporting requirements of the HH QRP for the CY 2023 program year represent $149 million in home health claims payment dollars during the reporting period out of a total $16.4 billion for all HHAs.

This proposed rule proposes to collect four additional items as standardized patient assessment data elements and replace one item collected as a standardized patient assessment data element beginning with the CY 2027 HH QRP. The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities. We also propose replacing the current Access to Transportation item with a revised Transportation (Access to Transportation) item beginning with the CY 2027 HH QRP. CMS is also proposing an update to the removal of the suspension of OASIS all-payer data collection to change all-payer data collection beginning with the start of care OASIS data collection timepoint instead of discharge timepoint. The net effect of these proposals is an increase of four data elements at the start of care time point and a net increase in burden.

Section VIII.B.1. of this proposed rule provides a detailed description of the net increase in burdens associated with the proposed changes. We proposed that additions of data elements associated with the HH QRP proposals would begin with January 1, 2027, discharges. The cost impact of these proposed changes was estimated to be a net increase of $12,604,894.62 in annualized cost to HHAs, discounted at 2 percent relative to year 2023, over a perpetual time horizon beginning in CY 2027. We described the estimated burden and cost reductions for these measures in section VIII. of this proposed rule. In summary, the implementation of proposals outlined in this proposed rule for the HH QRP is estimated to increase the burden on HHAs by $1,058.88 per HHA annually, or $12,604,894.62 for all HHAs annually.

3. Effects of the Expanded HH VBP Model

There are no proposed changes to the expanded HHVBP Model for CY 2025. Therefore, we assume there are no impacts resulting from this proposed rule. Furthermore, the public comments received related to the *Request for Information on Future Performance Measure Concepts for the Expanded HHVBP Model* and the update on *Future Approaches to Health Equity in the Expanded HHVBP Model,* included in section IV. of this proposed rule, will be summarized in the final rule and may inform proposals through future rulemaking.

4. Impacts of Home IVIG Items and Services

The following analysis applies to the home IVIG items and services payment rate as set forth in section V.D.1. of this proposed rule as added by section 4134 of the CAA, 2023 and accordingly, describes the impact for CY 2025 only. Table 49 represents the estimated aggregate costs of home IVIG users for CY 2025. We used CY 2023 data to identify beneficiaries actively enrolled in the IVIG demonstration (that is, beneficiaries with Part B claims that contain the Q2052 HCPCS code) to estimate the number of potential CY 2025 active enrollees in the new benefit, which are shown in column 2. In column 3, CY 2023 claims for IVIG visits under the Demonstration were again used to estimate potential utilization under the new benefit in CY 2025. Column 4 shows the proposed CY 2025 home IVIG items and services rate. The fifth column estimates the cost to Medicare for CY 2025 ($9,435,233). Table 50 represents the estimated impacts of the home IVIG items and services payment for CY 2025 by census region.

TABLE 49: ESTIMATED COSTS OF COVERED IVIG ITEMS AND SERVICES, CY 2025

Year	Number of Active Enrollees[1]	Number of IVIG Visits[1]	Proposed Nationwide Rate	Estimated Cost
CY 2025	1,933	21,892	$430.99	$9,435,233

[1]The number of active enrollees and IVIG visits in CY 2023 was used to estimate utilization in CY 2024 and CY 2025. Claims data were extracted on March 20, 2024.

TABLE 50—ESTIMATED IMPACTS OF THE HOME IVIG ITEMS AND SERVICES PAYMENT BY REGION, CY 2025

Region	States	Number of Active Enrollees[1]	Number of IVIG Visits[1]	Estimated CY 2025 Cost
New England	CT, ME, MA, NH, RI, VT	175	2,232	$961,970
Middle Atlantic	NJ, NY, PA	219	2,593	$1,117,557
South Atlantic	DE, DC, FL, GA, MD, NC, SC, VA, WV	504	5,220	$2,249,768
East North Central	IL, IN, MI, OH, WI	159	1,803	$777,075
East South Central	AL, KY, MS, TN	190	2,051	$883,960
West North Central	IA, KS, MN, MO, NE, ND, SD	136	1,591	$685,705
West South Central	AR, LA, OK, TX	196	2,168	$934,386
Mountain	AZ, CO, ID, MT, NV, NM, UT, WY	148	1,696	$730,959
Pacific	AK, CA, HI, OR, WA	214	2,538	$1,093,853
Other	GU, PR, VI	0	0	$0

[1]The number of active enrollees in the IVIG Demonstration and their IVIG visits in CY 2023 was used to estimate utilization in CY 2025. CY 2023 claims data were extracted on March 20, 2024. Each IVIG claims is assigned to a single census division. There are eight beneficiaries who had a set of IVIG claims in CY 2023 with a portion of their claims in one census division and the remaining claims in a different census division.

5. HHA CoP Changes: Establishing an Acceptance to Service Policy

We propose to add a new standard § 484.105(i), which sets forth a requirement for HHAs to establish an acceptance to service policy. All cost associated with this policy are located in the section VIII. of this proposed rule (Collection of Information). There are no transfers associated with this requirement.

6. Provider Enrollment Provisions

For purposes of applying a PPEO, we are proposing to expand the definition of ''new provider or supplier'' in § 424.527(a) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges under § 424.540(b). However, we are unable to establish an estimate of any potential burden associated with this provision for two main reasons. First, we do not have sufficient data upon which we can formulate a burden projection. Second, we cannot predict the scope, extent, and length of any future PPEO or the provider or supplier type(s) to which it may apply. Accordingly, we solicit public comment from stakeholders on the potential burden of our expansion of § 424.527(a).

7. Effects of the Proposed LTC Requirements for Acute Respiratory Illness Reporting

We propose to update the requirements related to reporting acute respiratory illnesses for LTC facilities at § 483.80(g). All cost associated with this policy are located in the section IX. of this proposed rule (Collection of Information). There are no transfers associated with this requirement. We welcome public comments on our estimates, and on ways that reporting burden can be minimized while still providing adequate data. We also welcome feedback on any challenges of collecting and reporting these data; ways that CMS could reduce reporting burden for facilities; and alternative reporting mechanisms or quality reporting programs through which CMS could instead effectively and sustainably incentivize reporting. Lastly, we welcome comments that address system readiness and capacity to collect and report these data.

D. 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 should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this proposed rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach used in estimating the number of entities reviewing this proposed rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. Therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. Finally, in our estimates, we have used the 948 number of timely pieces of correspondence on the CY 2024 HH PPS proposed rule as our estimate for the number of reviewers of this proposed rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. We seek comments on this assumption. Using the median hourly wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $106.42 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that

it would take approximately 2.77 hours for the staff to review half of this proposed rule. For each entity that reviews this proposed rule, the estimated cost is $294.78 (2.77 hours × $106.42). Therefore, we estimate that the total cost of reviewing this proposed rule is $279,451 ($294.78 × 948 reviewers).

E. Alternatives Considered

1. HH PPS

For the CY 2025 HH PPS proposed rule, we considered alternatives to the provisions articulated in section II.C. of this proposed rule. As described in section II.C.1.b. of this proposed rule, we proposed a mapping of three OASIS items (therapies, vision, and pain) in order to impute the responses from the OASIS–E to the OASIS–D to create simulated 60-day episodes from 30-day periods. We considered not proposing the mapping methodology; however, to continue with the best reading of the law and the finalized methodology for assessing behavior changes we proposed the OASIS mapping.

As described in section II.C.1.g. of this proposed rule, to achieve appropriate payments, we calculated a permanent adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, 2022, and 2023 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. One alternative to the proposed −4.067 percent permanent adjustment included halving the proposed permanent adjustment similar to how we finalized the permanent adjustment for CY 2024. Another alternative would be a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2025 permanent adjustment over a specified period of years, rather than halving the adjustment in CY 2025. Another alternative would be to delay the permanent adjustment to a future year. However, we believe that a reduction, a phase-in approach, or delay in the permanent adjustment would not be appropriate, as reducing, phasing in, or delaying the permanent adjustment would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger reduction to the payment rate in future years.

We also considered proposing to implement the one-time temporary adjustment to reconcile retrospective overpayments in CYs 2020, 2021, 2022, and 2023. However, as stated previously in this proposed rule, we believe that implementing both the permanent and temporary adjustments to the CY 2025 payment rate may adversely affect HHAs given the magnitude of the adjustment to the payment rate in a single year. Likewise, section 1895(b)(3)(D)(iii) of the Act gives CMS the authority to make any temporary adjustment in a time and manner appropriate though notice and comment rulemaking. Therefore, we believe it is best to propose only the implementation of the permanent decrease of 4.067 percent to the CY 2025 base payment rate.

Finally, we considered not proposing to adopt the OMB delineations listed in OMB Bulletin 23–01. However, we have historically adopted the latest OMB delineations in subsequent rulemaking after a new OMB Bulletin is released.

2. Home IVIG Items and Services

For the CY 2025 HH PPS proposed rule, we did not consider alternatives to implementing the home IVIG items and services payment for CY 2025 because section 1842(o)(8) of the Act requires the Secretary to establish a separate bundled payment to the supplier for all items and services related to the administration of intravenous immune globulin to an individual in the patient's home during a calendar day effective January 1, 2024.

F. Accounting Statements and Tables

1. HH PPS

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in table 51, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2025 HH PPS provisions of this proposed rule.

TABLE 51: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2024 TO CY 2025

Category	Transfers
Annualized Monetized Transfers	-$280 million
Bearers of Transfer Gain	Medicare HHAs

2. HH QRP

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in table 52, we have prepared an accounting statement showing the classification of the costs associated with the ICRs for the proposed HH QRP provisions in CY 2027.

TABLE 52: HH QRP ESTIMATED COSTS FROM CY 2025 TO CY 2027

Category	Costs
The total economic impact of these proposals including the addition of one Living Situation item, two Food items, and one Utilities item, and the modification of the current Transportation item proposed for implementation in CY 2027	$12,604,894.62 (2% Discount Rate)

3. Home IVIG Items and Services

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in table 53, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2025 IVIG provisions of this proposed rule.

TABLE 53: ACCOUNTING STATEMENT: IVIG CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS CY 2025

Category	Transfers
Annualized Monetized Transfers	$9.4 million*
Bearers of Transfer Gain	Medicare DMEPOS suppliers

*Reflects the CY 2025 aggregate transfer impact of the home IVIG items and services payments.

G. 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 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 $19 million [161] and approximately 96 percent of HHAs are considered small entities. Table 54 shows the number of firms, revenue, and estimated impact per home health care service category.

TABLE 54: 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 Average 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)/Number of firms. For the total, this is the average estimated impact across all number of firms.

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 result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule will have significant economic impact on a substantial number of small entities. Specifically, we estimate that the net impact of the policies in this proposed rule will have a significant impact on hospices in the

[161] *https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx.*

New England, Mid Atlantic, and Pacific regions, which is reflected in the last column in table 48 as a greater than 33 percent decrease in expenditures when comparing CY 2025 payments to estimated CY 2024 payments. The reason for the net decrease in CY 2025 is mostly driven by the impact of the permanent adjustment reflected in the third column of table 48. Further detail is presented in table 48, by HHA type and location.

Regarding options for regulatory relief, we note that section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of differences between the assumed behavior changes finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56455) and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Additionally, section 1895(b)(3)(D)(ii) and (iii) of the Act requires us to make permanent and temporary adjustments to the payment rate to offset for such increases or decreases in estimated aggregate expenditures through notice and comment rulemaking. While we find that the −4.067 percent permanent adjustment, described in section II.C.1.g. of this proposed rule, is necessary to offset the increase in estimated aggregate expenditures for CYs 2020 through 2023 based on the impact of the differences between assumed behavior changes and actual behavior changes, we will also continue to reprice claims, per the finalized methodology, and make any additional adjustments at a time and manner deemed appropriate in future rulemaking. As discussed previously, we also explored alternatives to the proposed −4.067 percent permanent adjustment including a phase-in approach, where we could reduce the permanent adjustment, by spreading out the CY 2025 permanent adjustment over a period of years. Another alternative would be to delay the permanent adjustment to a future year. However, we believe that a reduction to the permanent adjustment, a phase-in approach, or delay in the permanent adjustment would not be appropriate, as reducing, phasing in, or delaying the permanent adjustment would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger reduction to the payment rate in future years. We also considered proposing to implement the one-time temporary adjustment to reconcile retrospective overpayments in CYs 2020, 2021, 2022, and 2023. However, as stated previously in this proposed rule, we recognize that applying the full permanent and temporary adjustments to the CY 2025 payment rate may adversely affect HHAs, including small entities. We are soliciting comments on the overall HH PPS RFA analysis.

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 proposed 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 43 and 44 in the CY 2022 HH PPS final rule (86 FR 62407 through 62410) for our analysis of payment adjustment distributions by State, HHA characteristics, HHA size, and percentiles.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This proposed rule is not applicable to hospitals. Therefore, the Secretary has certified that this proposed rule would not have a significant economic impact on the operations of small rural hospitals.

H. 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 2024, that threshold is approximately $183 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $183 million in any one year.

I. 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 would not impose substantial direct costs on State or local governments.

J. Conclusion

In conclusion, we estimate that the provisions in this proposed rule will result in an estimated net decrease in home health payments of 1.7 percent for CY 2025 (−$280 million). The $280 million decrease in estimated payments for CY 2025 reflects the effects of the proposed CY 2025 home health payment update percentage increase of 2.5 percent ($415 million increase), a 0.6 percent decrease in payments due to the new higher FDL ratio, which will decrease outlier payments in order to target to pay no more than 2.5 percent of total payments as outlier payments ($100 million decrease), and an estimated 3.6 percent decrease in payments that reflects the effects of the permanent behavior adjustment ($595 million decrease). In addition, the estimated aggregate impacts of the home IVIG items and services payment for CY 2025 is $9.4 million. Lastly, the implementation of the HH QRP proposed policy is estimated to increase the costs to HHAs by $1,058.88 per HHA annually, or $12,604,894.62 in the aggregate for HHAs annually.

X. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 12, 2024.

List of Subjects

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing

homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

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 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 424.527 is amended by adding paragraph (a)(4) to read as follows:

§ 424.527 Provisional period of enhanced oversight.

(a) * * *

(4) A provider or supplier reactivating the provider's or supplier's Medicare enrollment and billing privileges in accordance with § 424.540(b).

* * * * *

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 3. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1395i, 1395hh and 1396r.

■ 4. Section 483.80 is amended by revising paragraph (g) to read as follows:

§ 483.80 Infection control.

* * * * *

(g) *Respiratory illness reporting*—(1) *Ongoing reporting.* The facility must electronically report information on acute respiratory illnesses, including influenza, SARS–CoV–2/COVID–19, and RSV.

(i) The report must be in a standardized format and frequency specified by the Secretary.

(ii) To the extent as required by the Secretary, this report must include all of the following data elements:

(A) Facility census (defined as the total number of residents occupying a bed at this facility for at least 24 hours during the week of data collection).

(B) Resident vaccination status for a limited set of respiratory illnesses, including but not limited to the following:

(1) Influenza.

(*2*) SARS–CoV–2/COVID–19.

(*3*) RSV.

(C) Confirmed, resident cases of a limited set of respiratory illnesses, including but not limited to the following:

(*1*) Influenza.

(*2*) SARS–CoV–2/COVID–19.

(*3*) RSV.

(D) Hospitalized residents with confirmed cases of a limited set of respiratory illnesses, including but not limited to the following:

(*1*) Influenza.

(*2*) SARS–CoV–2/COVID–19.

(*3*) RSV.

(2) *Public health emergency (PHE) reporting.* In the event that the Secretary has declared a national, State, or local PHE for an acute infectious illness or determined that a significant threat for one exists, the facility must also electronically report all of the following data elements in a standardized format and frequency specified by the Secretary:

(i) Relevant confirmed infections for staff.

(ii) Supply inventory shortages.

(iii) Staffing shortages.

(iv) Relevant medical countermeasures and therapeutic inventories, usage, or both.

PART 484—HOME HEALTH SERVICES

■ 5. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 6. Section 484.105 is amended by adding paragraph (i) to read as follows:

§ 484.105 Condition of participation: Organization and administration of services.

* * * * *

(i) *HHA acceptance to service.* An HHA must do both of the following:

(1) Develop, implement, and maintain through an annual review, a patient acceptance to service policy that is applied consistently to each prospective patient referred for home health care, which addresses criteria related to the HHA's capacity to provide patient care, including, but not limited to, all of the following:

(i) Anticipated needs of the referred prospective patient.

(ii) Case load and case mix of the HHA.

(iii) Staffing levels of the HHA.

(iv) Skills and competencies of the HHA staff.

(2) Make available to the public accurate information regarding the services offered by the HHA and any limitations related to types of specialty services, service duration, or service frequency. The information is reviewed at least annually.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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