[Billing Code: 4120-01-F]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424, 483, and 484

[CMS-1803-F]

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: Final rule.

SUMMARY: This final rule will 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 finalizes 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 finalizes a new standard for an acceptance-to-service policy in the HH conditions of participation (CoPs). Lastly, it updates provider and supplier enrollment requirements and changes to the long-term care reporting requirements for acute respiratory illnesses.

DATES: These regulations are effective on January 1, 2025.

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 general information about the IVIG Items and Services Payment, send your inquiry via email to HIT_IVIGpolicy@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 webpage 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 at kim.roche1@cms.hhs.gov or Diane Corning at diane.corning@cms.hhs.gov for information about long term care facility acute respiratory illness reporting.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary and Issuance of the Final Rule

A. Executive Summary

1. Purpose and Legal Authority

a. Home Health Prospective Payment System (HH PPS)

As required under section 1895(b) of the Social Security Act (the Act), this final rule updates the CY 2025 payment rates for home health agencies (HHAs) and the CY 2025 payment

rate for disposable negative pressure wound therapy (dNPWT) devices. This rule finalizes 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 finalizes a permanent adjustment to the CY 2025 home health base payment rate. In addition, this rule finalizes the recalibrated PDGM case-mix weights and updates 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; finalizes the proposal to adopt the most recent Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) delineations for the home health wage index; and finalizes an occupational therapy (OT) LUPA add-on factor and updates the physical therapy (PT), speech-language pathology (SLP), and skilled nursing (SN) LUPA add-on factors. Additionally, this rule updates 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).

b. 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 finalizing updated policies. We are finalizing a proposal to add four new assessment items and modify one assessment item on the OASIS, update the removal of the suspension of OASIS all payer data collection and summarize public feedback on future HH QRP quality measure (QM) concepts.

c. 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) summarizing comments we received on a request for information (RFI) related to potential future performance measure concepts.

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

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

e. Home Health CoP Changes

In section VI.A. of this final rule, we are finalizing a new standard at § 484.105(i) that will 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. As finalized, 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 finalized a policy that HHAs will be required to make specified information available to the public that is reviewed whenever services are changed, and no less often than annually.

f. 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 finalizing our proposal to expand the definition of "new provider or supplier" in § 424.527(a) (solely for purposes of applying a provisional period of enhanced oversight) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges.

g. Long-Term Care (LTC) Facility 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 finalized a requirement to replace these requirements with streamlined continued data reporting requirements for certain respiratory illnesses. We are also finalizing a requirement that LTC facilities submit additional, related data elements that could be activated in

the event of a future acute respiratory illness public health emergency (PHE). We are not finalizing our proposal to increase data reporting if a significant threat for a PHE for an acute infectious illness exists.

2. Summary of the Provisions of this Final Rule

a. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this final rule, we discuss comments related to the monitoring and data analysis on PDGM utilization.

In section II.C.1 of this final rule, we finalize a permanent adjustment to the base payment rate under the HH PPS. Additionally, we finalize 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 final rule, we 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 final rule, we finalize a policy updating the home health wage index using 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 also includes the CY 2025 national, standardized 30-day period final payment rate, the final CY 2025 national per-visit payment amounts updated by the home health payment update percentage, and the final OT, PT, SLP, and SN LUPA add-on factors. The final home health payment update percentage for CY 2025 is 2.7 percent. Additionally, this rule finalizes the CY 2025 FDL ratio to ensure that aggregate outlier payments do not 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 final rule, we finalize the CY 2025 payment rate for dNPWT devices.

b. Home Health Quality Reporting Program (HH QRP)

In section III. of this final rule, we finalizethe collection of 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 finalized for collection are: one Living Situation item, two Food items, and one Utilities item. We also finalize a policy to modify the current Transportation item beginning with the CY 2027 HH QRP. We are also proposed 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.

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

In section IV. of this final rule, we summarize comments received on 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).

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

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

e. Home Health CoP Changes

In section VI.A. of this final rule, we finalized a new standard at § 484.105(d) that will 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 have also

finalized a requirement 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 finalized a requirement that HHAs make specified information available to the public that is reviewed at least annually. In the proposed rule, we sought public comments on other factors that influence the patient referral and intake processes. In this final rule, we summarize comments received.

f. Provider and Supplier Enrollment Requirements

Section 1866(j)(3)(A) of the Act states that the Secretary may 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 finalizing our proposal 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.

g. 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 finalized to replace these requirements with streamlined continued data reporting requirements for certain respiratory illnesses. We are also finalizing additional, related data elements that could be activated in the event of a future acute respiratory illness PHE. We are not finalizing our proposal to increase data reporting if a significant threat for a PHE for an acute infectious illness exists.

3. Summary of Costs, Transfers, and Benefits

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 $85 million (0.5 percent). The $85 million increase in estimated payments for CY 2025 reflects the effects of the CY 2025 finalized home health payment update percentage of 2.7 percent ($460 million increase), an estimated 1.8 percent decrease* that reflects the effects of the permanent behavior assumption adjustment ($305 million decrease) and an estimated 0.4 percent decrease that reflects the effects of an updated FDL ($70 million decrease). *The estimated 1.8 percent decrease related to the finalized behavior assumption adjustment includes all payments, while the finalized -1.975 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 finalized 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 health emergency (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 $250,000 in total costs to Medicare fee-for-service (FFS).	To update the items and services payment under the home intravenous immune globulin benefit in accordance with section 4134 of the Consolidated Appropriations Act, 2023 (CAA, 2023).
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 $6,156,799 for all HHA's and $ $395,800 for an annual review. To make specified information publicly available, we estimate a onetime cost of $199,430 for all HHA's and $398,860 to update the policy 6 times per year.	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 finalized 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.

B. Issuance of the Proposed Rule

The proposed rule, titled "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," appeared in the **Federal Register** on July 3, 2024 (89 FR 55312) (hereinafter referred to as the CY 2025 HH PPS proposed rule or July 2024 proposed rule).

The proposed rule set forth proposed payment and policy changes to the Medicare Home Health prospective payment system for CY 2025, proposed changes regarding other programs and policies, as well as solicited comments.

In the sections of the rule that follow, we will present the proposed policies and summarize and respond to the public comments received.

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 will 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

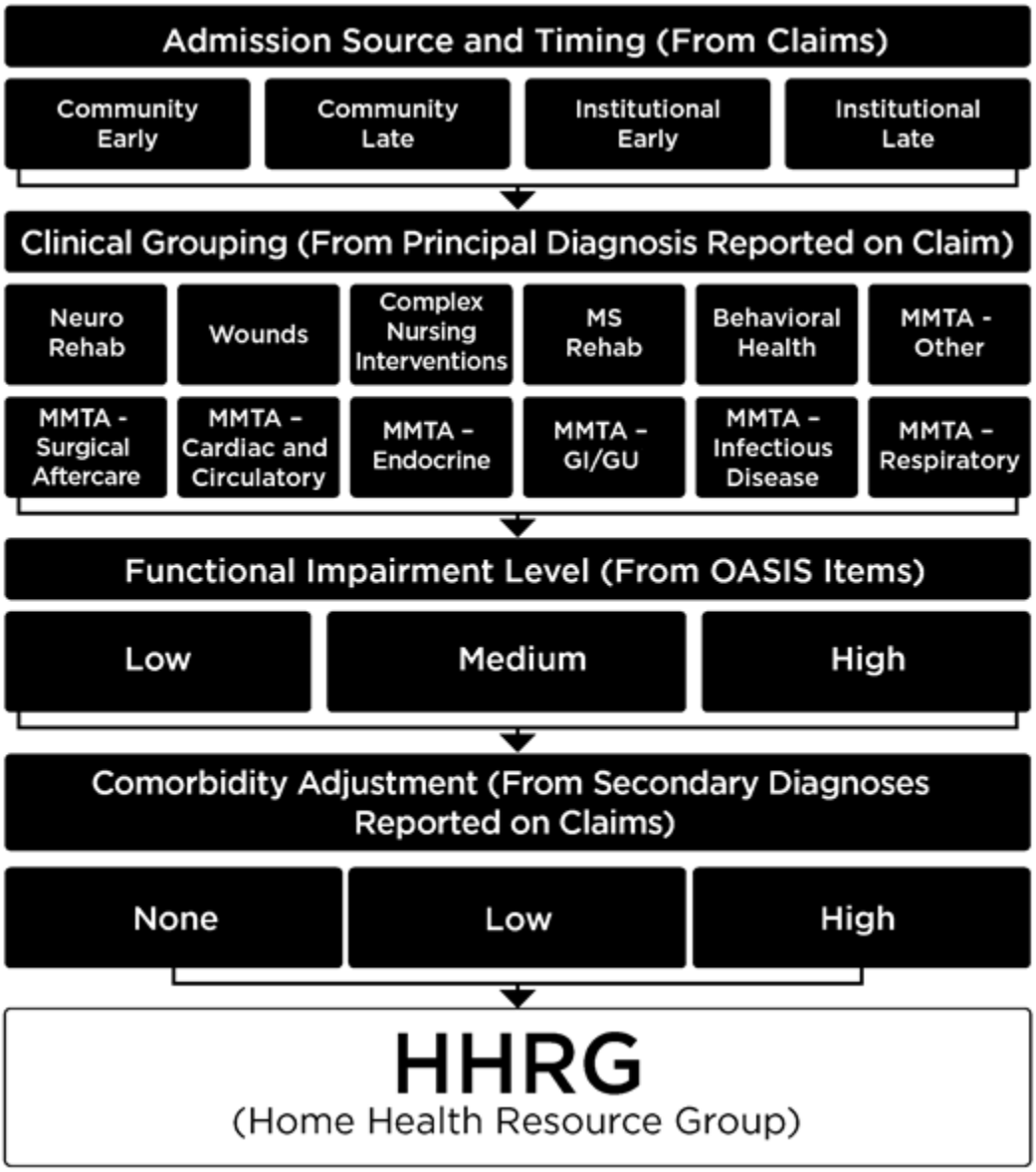
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The 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-guidanceguidancetransmittals2020-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).

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



B. Monitoring the Effects of the Implementation of PDGM

1. Routine PDGM Monitoring

The CY 2025 HH PPS proposed rule included analysis of Medicare home health benefit utilization, including 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. We also included 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.

Comment: Overall, commenters discussed the home health utilization trends presented in the monitoring concurrently with comments regarding access to the benefit and generally stated that they believe a decline in utilization is not related to a reduced need for home health services. These commenters encouraged CMS to develop policies that ensure that the PDGM does not continue to affect access to care as indicated by these declining utilization trends. A commenter also suggested CMS expand data collection to include geographic, racial, ethnic, socio-economic, sexual orientation, and gender identity to highlight disparities in home health care services.

Response: We will continue to monitor and analyze home health trends and vulnerabilities within the home health payment system and appreciate the commenter's suggestion for additional monitoring. We respond to comments discussing declining trends in utilization as they relate to access to care in our discussion in section B.1.f. of this final rule, and refer readers to that discussion.

C. CY 2025 Final Rule Payment Adjustments Under the HH PPS

1. Finalized Behavior Assumption Adjustments under the HH PPS

a. Background

As discussed in section II.A.1. of this final rule, starting in CY 2020, the Secretary was 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 the CY 2025 HH PPS proposed rule (89 FR 55318), our analysis continued 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 will 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 webpage 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 in the CY 2025 proposed rule, proposed 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 in the PDGM. 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 OASIS-E follow-up assessments as shown in the following figure 2.

FIGURE 2: ITEMS ASKED ON SOC/ROC AND NOT FOLLOW-UP ON OASIS-E

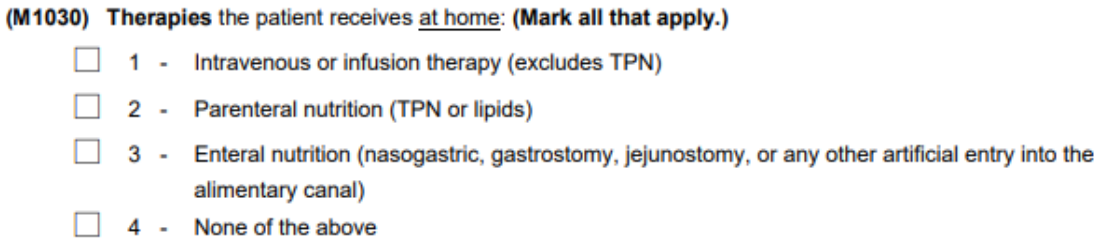
SOC/ROC
M1311. Current Number of Unhealed Pressure Ulcers/Injuries at Each Stage
M1322. Current Number of Stage 1 Pressure Injuries Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have a visible blanching; in dark skin tones only, 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 3, ask about therapies (M1030), vision (M1200), and the frequency of pain interfering with activity (M1242). Additionally, these items are only asked at SOC/ROC and not at follow-up in the OASIS-E.

FIGURE 3: OASIS-D ITEMS THAT DIFFER FROM OASIS-E



(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

To continue with our finalized methodology and create simulated 60-day episodes under the 153-group case mix system from 30-day periods under the PDGM, we need to impute the OASIS-D responses when we only have an OASIS-E available. 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.

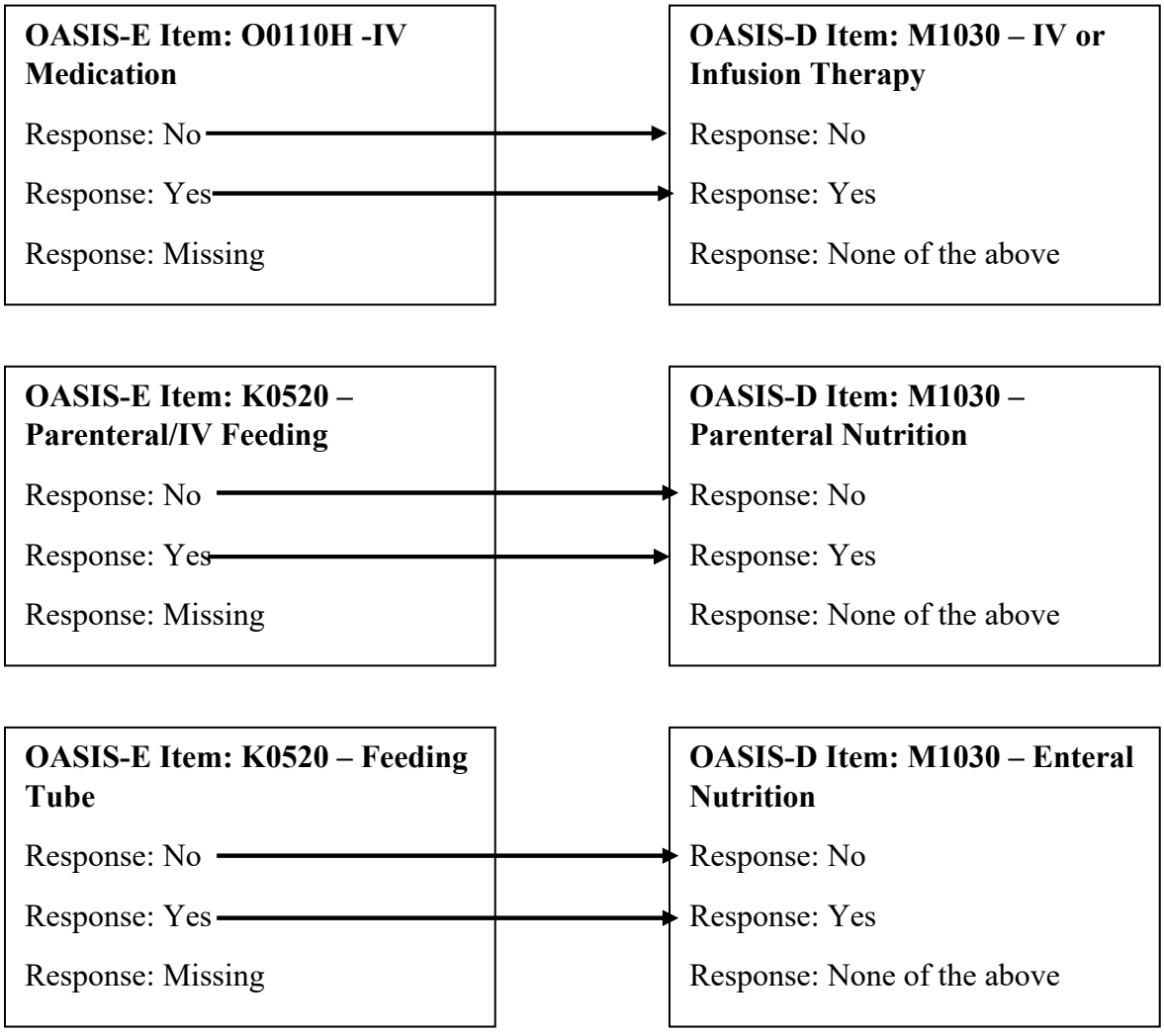
CMS proposed the following two assumptions to address the changes from the OASIS-D to the OASIS-E to continue to create simulated 60-day episodes from 30-day periods.

● If the simulated 60-day episode matches to a SOC or ROC assessment then we proposed to not impute the 13 items. If the simulated 60-day episode matches to a follow-up assessment, then we proposed 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 proposed that we would limit the look-back period to the beginning of the calendar year that precedes the calendar year for the claim. For example, for a simulated 60-day episode with a follow-up assessment on June 1, 2023, we would look back 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 proposed 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 proposed to use the OASIS-D for responses. If the simulated 60-day episode matches to an OASIS-E

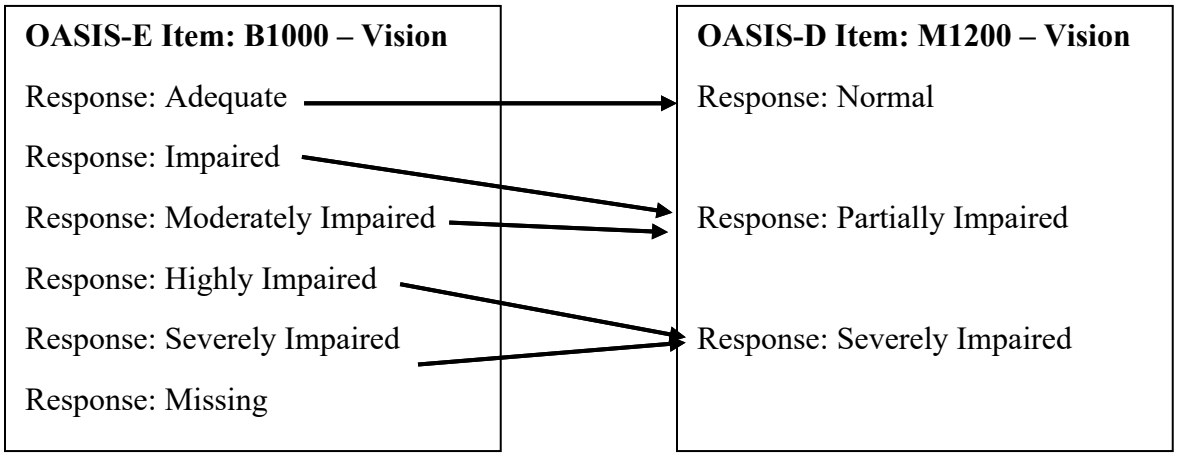
assessment, we proposed applying the following mapping for the therapies, vision, and pain items to impute responses as these responses are required for accurate payment calculation under the prior 153-group system. We also proposed applying the look-back period (that is, beginning of the calendar year that precedes the calendar year for the claim) as described in the assumption above, when necessary, when mapping claims.

FIGURE 4: THERAPIES MAPPING FROM OASIS-E TO OASIS-D



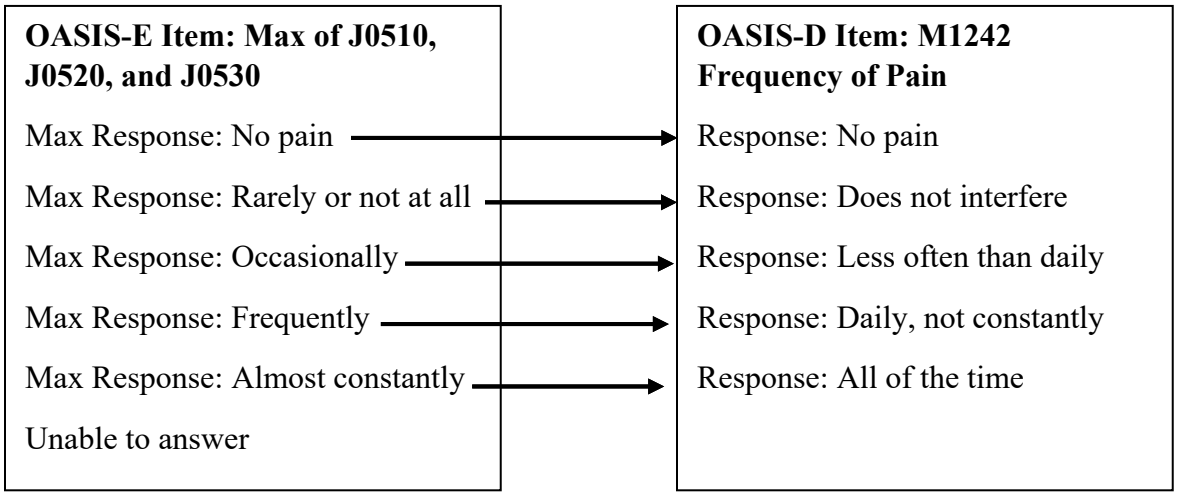
Note, if an OASIS-E assessment has a response of "no" to all three items (O0110H – IV medication, K0520 -Parenteral/IV feeding, and K0520 – Feeding Tube), as shown in figure 5, then the mapping for M1030 would be a response of "none of the above".

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



There was one pain item on the OASIS-D (M1242 – Frequency of Pain Interfering with patient's activity or movement) used for calculating payments. 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 stated that we believed 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 (pain interference with day-to-day activities) has a response of "occasionally", then we would use the response from J0520 ("frequently") for mapping as this is the most severe response. Figure 6 shows the proposed mapping based on the maximum severity response for each of the three pain items.

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



As the overall methodology was finalized in the CY 2023 HH PPS final rule (87 FR 66804), the two proposed assumptions described previously are simply technical updates based on the updated OASIS instrument 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 overall methodology with detailed instructions for each step. We received a few comments on the proposed assumptions related to mapping of the OASIS-E items.

Comment: A commenter supported the proposed assumptions. Another commenter expressed concerns related to the difference in the versions of questions used for mapping and a potential two-year lookback period. While the commenter did not present an alternative for mapping the three items missing from OASIS-E, the commenter did recommend a narrower lookback period of no more than three months.

Response: We appreciate the commenter's thoughtful review and recommendations. We carefully reevaluated the crosswalk and found a three-month lookback period could significantly decrease the number of claims available for analysis, as well as skew the data to potentially more clinically severe patients, for example, this would generally limit the data to those patients who

are discharged after an inpatient admission directly to home health care. A significant decrease in the total number of claims or in a particular type of claim (for example, community late) may not fully represent the population of home health patients. However, using an almost two-year look-back period for an assessment may not provide the most updated functional status of a beneficiary for the claim being analyzed, as a patient's functional impairment status may have changed (increased or decreased) in a longer look-back period. Balancing the need for adequate and unbiased data with the need for up-to-date data, we evaluated using a 12-month look-back period and found this timeframe provided the most complete and accurate data possible. It provides a sufficient number of claims while also allowing for the use of more updated assessment data than would have been used in a 24-month look-back period.

Final Decision: After consideration of the public comments and reevaluation of the proposed timeframe, we are finalizing the following assumptions for the OASIS-D to OASIS-E crosswalk:

● If the simulated 60-day episode matches to a SOC or ROC assessment then we will not impute the 13 items. If the simulated 60-day episode matches to an OASIS-E follow-up assessment, then we will 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 will limit the look-back period to 12-months. For example, a simulated 60-day episode that began on June 1, 2023, and linked to a follow-up assessment will be limited to a 30-day period that ended on or after June 1, 2022, and linked to a SOC or ROC assessment. If we cannot find a SOC or ROC assessment in that time period, we will exclude the claim from analysis.

● If the simulated 60-day episode matches to an OASIS-D assessment, then we will use the OASIS-D for the three items (therapies (M1030), vision (M1200), and the frequency of pain interfering with activity (M1242)) responses. If the simulated 60-day episode matches to an OASIS-E assessment, we will apply the mapping for the therapies, vision, and pain items as

shown in figures 4 – 6 to impute responses as these responses are required for accurate payment calculation under the prior 153-group system. When necessary, we will also apply the same 12-month look-back period as described in the previous assumption.

c. Calculating Permanent and Temporary Payment Adjustments

To offset prospectively for such increases or decreases in estimated aggregate expenditures resulting from 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 calculated 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 used 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.

Comment: Several commenters continue to oppose the behavior adjustment methodology finalized in the CY 2023 HH PPS final rule and repeated objections discussed in the CY 2023 HH PPS final rule and CY 2024 HH PPS final rule, stating that they believe the methodology violates the Social Security Act and performs an unauthorized rebasing of the 30-day payment rate. Commenters again requested that CMS develop and propose a new methodology.

Response: The comments received on the methodology for the proposed rule are similar to those received during CY 2023 and CY 2024 rulemaking. We refer readers to our responses to those comments in the CY 2023 HH PPS final rule (87 FR 66797 through 66804) and CY 2024 final rule (88 FR 77689). In those rules, we responded to commenters' statements that they believe our final methodology was a violation of the Social Security Act, as well as commenters' technical concerns, such as the inclusion of therapy visits as part of our methodology. In this year's proposed rule, we did not propose any changes to the behavior adjustment methodology, as we finalized this methodology to evaluate the impact of the differences of assumed versus actual behavior changes on estimated aggregate expenditures, which is an ongoing evaluation for all the years in which a payment adjustment is appropriate.

d. CY 2023 Final Claims Results

We will continue the practice of using the most recent complete home health claims data available at the time of rulemaking. The CY 2023 analysis presented in the CY 2025 HH PPS proposed rule was considered preliminary and as additional data became available from the latter half of CY 2023, we updated our results in this final rule. While the claims data and the permanent and temporary adjustment results in this final rule 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 final 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 final 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 webpage for more information.[1] In addition, the final CY 2025 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH PPS Regulations and Notices webpage,[2] 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 to apply for all the years in which an adjustment is appropriate, 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.

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[1] https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.
[2] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.

Using the final CY 2023 dataset, we began with 8,319,064 30-day periods of care and dropped 513,580 30-day periods of care that had a claim occurrence code 50 date after October 31, 2023. We also excluded 866,308 30-day periods of care that had a claim occurrence code 50 date before January 1, 2023, to ensure the 30-day period will 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 13,508 30-day periods were excluded.

Additionally, we excluded 204,597 simulated 60-day episodes of care where no OASIS information was available in the Chronic Conditions Data Warehouse (CCW) Virtual Research Data Center (VRDC), a recent SOC/ROC OASIS was not available, a wage index was not available, or the episode could not be grouped to a Health Insurance Prospective Payment System (HIPPS) code 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 (69.0 percent) and single 30-day periods of care (31.0 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 final rule included 6,541,678 actual 30-day periods of care and 3,870,602 simulated 60-day episodes of care for CY 2023.

Using the final dataset for CY 2023 (6,541,678 actual 30-day periods which made up the 3,870,602 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 $1,875.46 based on actual behavior, as shown in table 2. 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 -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 weight 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 ($1,875.46). 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 final claims data are shown in table 2.

TABLE 2: CY 2023 FINAL 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*	$1,875.46	**Permanent** -1.004%
Aggregate Expenditures	$16,354,432,797**	$15,383,001,684	**Temporary** -$971,431,113

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW July 11, 2024.
*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 2) 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 ($16.4 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 2, a permanent prospective adjustment of -1.004 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. We remind readers, the permanent prospective adjustment of -1.004 percent is for illustrative purposes only and the annual (single year) permanent adjustment cannot be added to previous annual adjustments. To illustrate the annual calculation for CY 2023 claims only:

$$\frac{(\$1{,}875.46 - \$1{,}894.49)}{\$1{,}894.49} = -1.004\ \%$$

Section 1895(b)(3)(D) of the Act requires us 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 four years of claims data (CYs 2020 – 2023) under the PDGM, with one of these years including a partial permanent adjustment. Later we provide an illustration of the annual (single year) permanent adjustments calculated on the discrete year of claims. We remind readers these annual adjustments cannot be added or multiplied together to determine the total permanent adjustment needed for CY 2025 because each individual year requires an assumption that all prior adjustments were taken. We provided an illustrative equation in the CY 2025 HH PPS proposed rule (89 FR 55335) using the annual adjustment. We remind readers that equation may result in slightly different results due to the underlying assumptions each year and rounding.

TABLE 3: TOTAL ANNUAL PERMANENT ADJUSTMENT FOR DISCRETE CLAIMS IN CYs 2020 - 2023

Claims Data	Annual Permanent Adjustment	HH PPS Final Rule Citation
CY 2020	-6.52%	87 FR 66805
CY 2021	-1.42%	87 FR 66806
CY 2022	-1.767%	88 FR 77692
CY 2023	-1.004%	table 2 of this rule

Additionally, we determined that our initial estimate of the base payment rate ($2,010.69) resulted in excess expenditures of approximately $971 million in CY 2023. This will require a temporary adjustment, where the dollar amount ($971 million) will be converted to a factor when implemented, to offset for such increases in estimated aggregate expenditures for CY 2023.

f. CY 2025 Final Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we describe how we annually analyzed CY 2023 final claims data to determine the effects of actual behavior change on estimated aggregate expenditures. Again, that analysis included simulations that assumed that the -5.779 percent payment adjustment was already taken. We note that CMS implemented a payment adjustment of -2.890 percent for CY 2024, rather than the -5.779 percent we calculated (88 FR 77697), so the calculations set forth later in this section reflect the remaining adjustments that are still needed.

Therefore, the calculation in this section includes any of the remaining adjustments not applied in previous years (that is, CYs 2020 to 2022 claims data), 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 3, we do not assume the full adjustment from prior years had been taken.

As discussed in section II.C.1.d. of this final rule, using the final dataset for CY 2023 (6,541,678 actual 30-day periods which made up the 3,870,602 simulated 60-day episodes) we determined the CY 2023 30-day base payment rate should have been $1,875.46 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 4, 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 $1,875.46 (based on actual behaviors) is the total permanent adjustment need for CYs 2020 through 2023 claims.

TABLE 4: 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	$1,875.46	-6.726%*

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW July 11, 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 that for CY 2025 we must also account for adjustment made in CY 2024.

As shown in table 4, a permanent prospective adjustment of -6.726 percent to the CY 2025 30-day payment rate for CYs 2020 through 2023 will be required to offset for such increases in estimated aggregate expenditures in future years. To illustrate this calculation:

$$\frac{(\$1{,}875.46 - \$2{,}010.69)}{\$2{,}010.69} = -6.726\ \%$$

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 will 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 5, a permanent prospective adjustment of -6.726 percent to the CY 2025 30-day payment rate will 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 will include estimated aggregate expenditures in CY 2023, by simply subtracting the -2.890 percent applied in CY 2024 from the total permanent adjustment of -6.726 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 $(1 - 0.0289) \times (1 - x) = (1 - 0.06726)$. To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1-0.06726}{1-0.0289}\right)$$
$$x = 1 - 0.96050$$
$$x = 0.03950 \text{ (that is, 3.95 percent)}$$

In table 5 we provide the base payment rate for assumed behaviors (what CMS actually paid), the recalculated base payment rate for actual behaviors (what CMS should have paid), the

total permanent adjustments calculated from the base payment rates (accounts for any adjustments taken prior), and the permanent adjustment applied.

TABLE 5: 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% (88 FR 66808)
CY 2022	$2,031.64	$1,839.10	-5.78%	-2.890% (88 FR 77697)
CY 2023	$2,010.69	$1,873.17	-3.95%	see final decision
CY 2024	$2,038.13	TBD	TBD	TBD
CY 2025	TBD	TBD	TBD	TBD
CY 2026	TBD	TBD	TBD	TBD

Note: 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.

In the CY 2025 HH PPS proposed rule (89 FR 55337), we proposed to apply the full permanent adjustment we (then) calculated of -4.067 percent, noting that we would update this percentage using more complete claims data in the final rule, to 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. Using more complete claims data, and as calculated previously, the permanent adjustment to the CY 2025 30-day payment rate would be a reduction of 3.95 percent.

We remind readers that while we have not yet proposed a methodology on how CMS will apply the temporary adjustment on a prospective basis to the base payment rate, we finalized the methodology for determining the temporary adjustment dollar amount in the CY 2023 HH PPS final rule (87 FR 66804). 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 the CY 2025 HH PPS proposed rule (89 FR

55337), 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. In other words, the total dollar amount for the temporary adjustment will not change as data analysis in the final rules are considered complete. In table 6, we provide the temporary adjustment dollar amount for each year and the overall total.

TABLE 6: SUMMARY OF TEMPORARY ADJUSTMENTS DOLLAR AMOUNTS 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	- $971,431,113
CY 2024	TBD
CY 2025	TBD
CY 2026	TBD
Total	-$4,460,954,477

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 July 11, 2024.
Note: The anticipated temporary adjustments of approximately $4.5 billion will require temporary adjustment(s) to offset for such increases in estimated aggregate expenditures. The dollar amount will be converted to a factor when implemented in future rulemaking.

We did not propose to take the temporary adjustment in CY 2025. In future rulemaking, we will propose the temporary adjustment dollar amount to be converted to a factor to be applied to the national, standardized base payment rate in a time and manner determined appropriate.

Comment: Commenters stated that they believe CMS has not provided data, or that they believe the data presented is inaccurate to demonstrate behavior changes, and therefore, they believe any payment adjustment is not supported.

Response: We disagree that we have not provided commenters with the data on which we relied, or that we relied on inaccurate data. We provided our extensive data in the CY 2022 HH PPS proposed rule (86 FR 35880 through 35889), the CY 2023 HH PPS proposed rule (87 FR 37605 through 37614), the CY 2024 HH PPS proposed rule (88 FR 43663 through 43671), and the CY 2025 HH PPS proposed rule (89 FR 55318 through 55327). 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 the materials from the webinar, including the presentation and the data files were published on the CMS website.[3] As stated previously, CMS also provides twice a year (that is, proposed and final rules) the HH PPS LDS file and the Home Health Descriptive Statistics from the LDS Files. Therefore, CMS has provided this data numerous times through rulemaking and made all data files used in assessing behavior changes and rate setting available for interested parties.

Comment: The majority of commenters opposed the proposed permanent adjustment to the CY 2025 home health rate and requested CMS postpone its application in order to preserve access to home health services and the scope of care available. Commenters stated that they believe CMS dismissed data analysis presented from interested parties showing an increase in referral rejections, which commenters purport is caused by the permanent rate adjustment. These commenters stated that this "on-going pattern of loss of access to care" is directly related to implementation of the PDGM and payment adjustments related to the behavior adjustment analysis and that CMS has an obligation to answer the questions posed through these analyses. The most common themes commenters presented as support for their concern that another permanent adjustment in CY 2025 is exacerbating an unstable home health benefit are negative margins, increasing costs, labor shortages, and increasing referral rejections by HHAs.

Response: We diligently review all comments and analysis from interested parties submitted through public comment on proposed rules. Our review of data and comments provided by interested parties, as well as our own internal data and analysis, helps the agency implement appropriate payment policies. This thorough process helps guide agency decision making, as we have discretion to implement regulations and payment adjustments in a time and

[3]Home Health Patient-Driven Groupings Model webpage at https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/hh-pdgm.

manner deemed appropriate. Throughout the policy-making process, we monitor the effects the PDGM and Medicare home health payment rates have on access to care, including the number of beneficiaries accessing the benefit as well as the number of providers furnishing services. We carefully analyze our own data extracted through the CCW VRDC, claims review, and examination of cost reports. CMS also monitors the effects of the PDGM on the quality of care provided by HHAs through the home health quality reporting program (HH QRP),[4] and we refer readers to section III of this rule for further information about the HH QRP. To the extent commenters suggest access to care concerns mean we should not make any behavioral adjustments, such concerns cannot override our statutory obligations. As for the suggestion that access to care issues justify delaying implementation of the permanent behavioral adjustments, our analysis has not identified sufficient evidence that delaying the implementation of the permanent adjustment will have a significant effect on access to care or the issues commenters describe as destabilizing the home health benefit. Below, we respond to these concerns and discuss potential influencing factors that may affect the home health industry beyond the permanent behavioral adjustments.

We understand that commenters are concerned that the PDGM might have narrowed the gap between the margins providers receive treating patients enrolled in Medicare-FFS and the margins providers receive from patients with other health coverage. However, as we stated in the CY 2023 HH PPS final rule (87 FR 66807) and the CY 2024 HH PPS final rule (88 FR 77695), Medicare does not set payments to cross-subsidize other payers, as we are mindful of our obligation to be responsible stewards of the Medicare Trust Funds. Many commenters stated outright that Medicare should consider all-payor margins when evaluating the accuracy of the Medicare home health payment rate. While CMS analyzes Medicare margins as a financial gauge overall to the soundness of the home health industry, we again note that 42 CFR 413.5 states that "costs attributable to other patients of the institution are not to be borne by the

[4]https://www.cms.gov/medicare/quality/home-health.

program"—"the program" being Medicare. In other words, when setting payment rates, CMS is not required to consider any shortfalls or deficits created by the payment rates of insurance programs covering other patients.

Our analysis of cost reports submitted by HHAs shows that Medicare payment rates exceed costs of care by 32 percent (89 FR 55321). Overall, CMS's data on the cost of providing care (as reported by HHAs on the Home Health Medicare Cost Reports (CMS Form 1728-20, OMB No. 0938-0022)) and the margin analysis presented in the CY 2024 HH PPS final rule (88 FR 77695), along with data reported by MedPAC, an independent congressional agency,[5] indicate that the cost of providing home health care remains, on average, below the base payment rate and that HHAs in general continue to experience high Medicare margins. We also note that we reviewed an annual outlook survey[6] of 152 home health market participants (72 percent of which were executives, *see* page 4) published by Homecare Homebase (HCHB), an electronic health records service provider to home health agencies that report their software serves "all ten of the top ten largest home health agencies."[7] Approximately 85 percent of survey participants reported they expect their organization's overall revenue to stay the same (20 percent) or increase (65 percent) in 2024 compared to 2023 (pg. 7). We understand this survey is only a sample and may not represent every HHA; however, it is important to recognize that many home health executives report an overall positive market outlook despite the permanent adjustment to the home health payment rate implemented in CY 2023.

We acknowledge commenters' concerns regarding staff shortages. Similar to what we stated in the CY 2024 HH PPS final rule (88 FR 77696), we recognize there are widespread staffing shortages across the spectrum in healthcare as well as the general labor market. But the statute limits behavioral adjustments to those attributable to the implementation of the PDGM,

[5]https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.
[6]https://hchb.com/resources/white-papers/survey-2024-hhcn-outlook-survey-and-report/.
[7]https://hchb.com/faqs/.

and commenters do not cite evidence suggesting staffing shortages are attributable to those changes. We primarily account for those challenges in other ways, such as the market basket as explained in section II.C of this final rule. As we stated above and previously, delaying the permanent adjustment now will only lead to larger permanent adjustments in the future, and any temporary savings by HHAs will be offset by larger future temporary adjustments.

We also considered the referral analysis industry advocates again submitted using their proprietary data. While we welcome analysis conducted by industry advocates and incorporate insights from the industry's experience and data as appropriate, for reasons including those explained in the CY 2024 HH PPS final rule (88 FR 77695), we must use Medicare FFS data to set Medicare FFS policy. We appreciate that the industry advocates addressed some of the concerns with their data that we raised last year. However, they did not address whether their proprietary data contains information from other payors, such as Medicare Advantage (MA) plans.

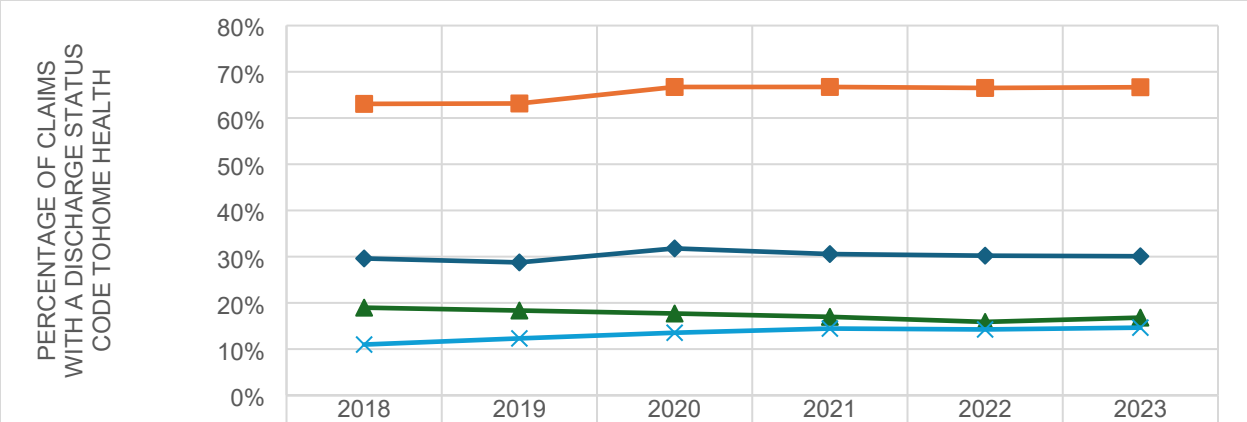
It is important to note that neither our nor the industry's analysis of referral rejections studied causation. In other words, an increase of non-acceptance to home health does not necessarily indicate that delaying the payment adjustment would increase referral acceptance. The industry appears to assume that the main reason an HHA would reject a referral is because the HHA cannot afford to provide the services for the referred patient based on the Medicare home health payment rate. As noted above, CMS's analysis of home health costs suggests the payment rate is adequate to provide services to beneficiaries, and any number of reasons exist that could result in a patient not receiving home health services. For instance, not every patient is found to be eligible for home health upon initial assessment and some patients decline home health despite being referred. Additionally, HHAs decide which services they can provide (in addition to skilled nursing) and may not be appropriately staffed to provide the services in the patient's plan of care. For example, a patient may need skilled nursing, physical therapy, and occupational therapy, but the referred HHA is not appropriately staffed with (or contracted with)

an occupational therapist. Therefore, even large increases in referral rejections would not necessarily justify delaying the permanent adjustment or substantiate concerns that HHAs cannot afford to accept patients based on the national-standardized payment rates.

Nevertheless, based on the industry's suggestion that their data suggests that there has been an increase in referral rejections since we implemented the PDGM, we conducted our own referral analysis using Medicare FFS data, and our findings, as shown in figure 7, differ from the industry's. We acknowledge that there will always be a certain percentage of referral rejections, for example, patient refusal or ineligibility, and our analysis indicates that the rejection rate has been relatively stable with less than a five percent change from CY 2020 to 2023.

In conducting our referral analysis, we first determined "referrals" by identifying FFS acute inpatient, inpatient rehabilitation facility (IRF), skilled nursing facility (SNF), and outpatient claims that had a discharge status code indicating home health. While a beneficiary may be counted more than once (for example, multiple inpatient admissions in a year), each claim with a discharge to home health is considered its own referral. Figure 7 illustrates the percentages of claims with a discharge status code indicating home health services.

FIGURE 7: PERCENTAGE OF CLAIMS WITH A DISCHARGE STATUS CODE INDICATING HOME HEALTH SERVICES FOR CYS 2018 – 2023



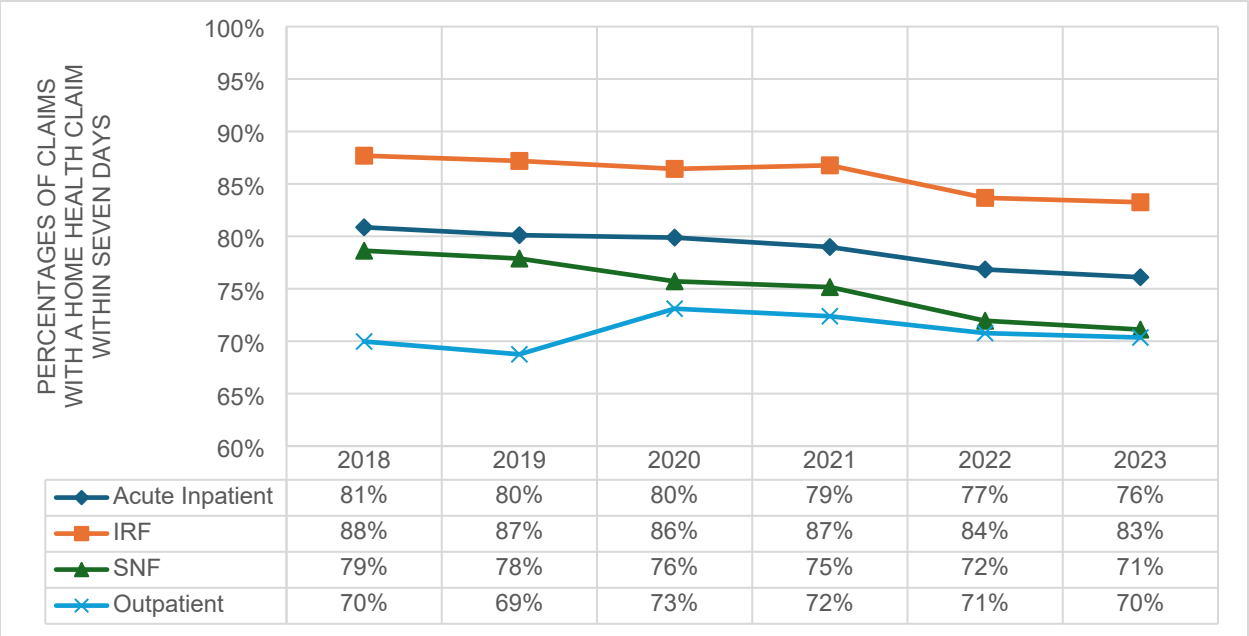
	2018	2019	2020	2021	2022	2023
Acute Inpatient	30%	29%	32%	31%	30%	30%
IRF	63%	63%	67%	67%	67%	67%
SNF	19%	18%	18%	17%	16%	17%
Outpatient	11%	12%	14%	14%	14%	15%

Source: CY 2023 Medicare FFS claims accessed on the CCW September 4, 2024.
Note: Analysis is at the claim level to represent each potential referral to home health. Therefore, a beneficiary can be represented multiple times in the analysis.

We found from 2018 to 2023 referrals to home health services from acute inpatient claims remained stable, increased for IRF claims, decreased for SNF claims, and increased for outpatient claims.

Next, utilizing the same time period (CYs 2018-2023), we excluded any home health claims where the beneficiary did not have an acute inpatient, IRF, SNF, or outpatient claim preceding the home health claim. We specifically looked at acute inpatient, IRF, SNF or outpatient claims because this is the clearest way to determine that the beneficiary was referred to home health based on the discharge status codes. We then analyzed the number of days between the acute inpatient, IRF, SNF, and outpatient claim (with a discharge status code to home health) through date and the home health claim from date. Per 42 CFR 484.55(a)(1) the initial assessment visit must be held within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician or allowed practitioner-ordered start of care date. Therefore, we limited our analysis to a home health claim start date within seven days of the non-home health claim through date. For example, an acute inpatient claim has a through-date of January 31st, and the same beneficiary has a home health claim start date on or before February 7th. Figure 8 illustrates the percentage of acute inpatient, IRF, SNF, and outpatient claims that had a discharge status code to home health and the beneficiary having a home health claim within seven days of discharge from an acute inpatient, IRF, SNF, or outpatient setting.

FIGURE 8: PERCENTAGE OF NON-HOME HEALTH CLAIMS WITH A HOME HEALTH CLAIM WITHIN SEVEN DAYS OF DISCHARGE BY CLAIM TYPE FOR CYS 2018 – 2023



	2018	2019	2020	2021	2022	2023
Acute Inpatient	81%	80%	80%	79%	77%	76%
IRF	88%	87%	86%	87%	84%	83%
SNF	79%	78%	76%	75%	72%	71%
Outpatient	70%	69%	73%	72%	71%	70%

Source: CY 2023 Medicare FFS claims accessed on the CCW September 4, 2024.
Note: Analysis is at the claim level to represent each potential referral to home health. Therefore, a beneficiary can be represented multiple times in the analysis.

Our analysis shows on average, beneficiaries with acute inpatient, IRF, SNF, and outpatient claims had a home health claim within seven days of discharge: 79 percent, 86 percent, 75 percent, and 71 percent, respectively from 2018 to 2023. Overall, we found, on average, 80 percent of referrals from acute inpatient, IRF, and SNF claims have a home health claim within seven days of discharge, while outpatient had 71 percent of referrals on average. In our analysis we found an average of 80 percent, 79 percent, and 75 percent acceptance of referrals for 2018 (pre-PDGM), 2020 (PDGM), and 2023 (PDGM) respectively for Medicare FFS beneficiaries.

Our analysis shows that there is a 4.2 percent reduction in the referral acceptance rate between 2020 and 2023 which is less than half the approximate 10 percent reduction in the referral acceptance rate the industry found in that same time. We note that we do not expect that all referrals to home health would result in acceptance of those referrals. As mentioned previously, there are several reasons for non-acceptance of a referrals, including patient ineligibility for home health services. The purpose of the referral analysis shown in this final rule is to compare the Medicare FFS referral rejection rate to the industry's analysis of the referral

rejection rate using their proprietary data. The industry reported an approximate 77 percent, 75 percent, and 65 percent acceptance of referrals for 2018 (pre-PDGM), 2020 (PDGM), and 2023 (PDGM) respectively for their study population. One reason for the different results could be the different population the industry studied. As described in the CY 2025 HH PPS proposed rule (89 FR 55319) there was a total of about 17.1 million unique FFS beneficiaries from 2018 to 2023.[8] Commenters stated that their referral analysis was "based on 25.7 million patients who entered Homecare Homebase from 2018 through the present." It is unclear why the Homecare Homebase data included an additional 8.6 million patients. One possibility is that that Homecare Homebase's database included patients who were not enrolled in Medicare FFS or used other payors. As explained above, we set Medicare FFS policy based on how it affects Medicare FFS beneficiaries—not how it affects other payors' enrollees.

Comment: Commenters also highlighted a decrease in the number of HHAs since the implementation of the PDGM and this decrease may be contributing to the lack of access to care and increased referral rejections.

Response: In the CY 2024 HH PPS final rule (88 FR 77696) we stated awareness of changes in the home health industry. We acknowledged that the home health landscape is changing as HHAs continue to be consolidated and bought by private equity firms and the increase of for-profit agencies. For example, in our data we identified a total of 8,674 HHAs that had ownership status available, and 82 percent are for-profit; 15 percent are non-profit, and 3 percent government owned. In their 2024 report, MedPAC describes a continuous decline in the number of HHAs since 2013, while the supply of agencies remained relatively stable after the implementation of PDGM in 2020.[9] MedPAC also notes that relative to the FFS Medicare

[8]Some beneficiaries may be counted across years, and therefore the total may overestimate the total number of beneficiaries between 2018 and 2023.

[9]Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy*, Washington, D.C. (March 2024) - https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch7_MedPAC_Report_To_Congress_SEC.pdf.

population alone, the supply of agencies increased (to 2.3 HHAs per 10,000 FFS beneficiaries) because the 2022 decline in FFS Medicare beneficiaries was greater than the decline in the number of agencies. Further, our own analysis shows that there is only a 1.7 percent decline in the number of HHAs with at least one claim in 2019 to the number of HHAs with at least one claim in 2023, and the vast majority of Medicare beneficiaries live in counties with a few HHAs with positive margins. While the distribution of HHAs have changed, there is no evidence to support that this is solely attributable to adjustments to the home health payment rates and, again, note that the change in ownership practices could be contributing to the slight decline in the number of HHAs.

Comment: We have continued to receive concerns from commenters regarding "inappropriate practice patterns," suggesting again that HHAs may change how they operate in accordance with payment. In response to the CY 2025 HH PPS proposed rule, CMS received many letters from therapists and other home health care practitioners detailing administrative mandates from HHAs limiting how many visits a patient may receive. Further, many of these commenters stated that it was not their salary that would cause them to leave the home health environment, but the strict direction detailing the limits of their practice in order to generate profit for the agency.

Response: These comments mirror comments we responded to in last year's HH PPS final rule discussing the potential for the functional impairment levels to create an incentive for HHAs to hand-pick patients based on their predicted case mix grouping. We again emphasize that the plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. It is improper for an HHA to influence a practitioner on what should be included in the plan of care based on the HHA's own financial constraints and staffing abilities. As stated in the CY 2024 HH PPS final rule (88 FR 77699), we

expect the provision of services be made to best meet the patient's care needs and in accordance with the home health CoPs at § 484.60, and that it is not proper for HHAs to under-supply care or services or reduce the number of visits in response to payment, as this would be a violation of the CoPs.

A commenter summed up many of these comments by stating that "rate cuts lead to care cuts." We acknowledge commenters' concerns that they believe HHAs are dictating practice patterns in response to the implementation of the PDGM. However, Medicare sets payment rates in accordance with statutory requirements, and not HHA's business practices.

Moreover, access to care is impacted by many factors. This may include factors as varied as labor conditions, patient mix, industry margins, and competitive pressures. Congress changed the home health prospective payment system in the BBA of 2018 and instructed CMS to further adjust payment rates to account for differences between the behavior changes we predicted in the CY 2019 rule and the actual behavior changes we have observed since the implementation of the PDGM in CY 2020. We are implementing these payment adjustments in a time and manner appropriate in accordance with the law, while mindful of possible disruptions this implementation may cause to the services to which beneficiaries are entitled. Our analysis continues to suggest that the permanent adjustment we are finalizing here to the CY 2025 base payment rate should not materially affect access to the Medicare home health benefit.

Final Decision: We continue to adhere to the methodology finalized in the CY 2023 HH PPS final rule (87 FR 66804). However, as in previous years, we are committed to remaining responsive to commenter concern regarding on-going permanent rate adjustments. We acknowledge that while we must comply with the statutory requirement that CMS ensure the estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that would have been made under the prior system, we have the discretion to implement any adjustment in a time and manner determined appropriate. Therefore, in response to commenter concerns, we are finalizing a -1.975 percent (half of the proposed -3.95 percent)

permanent adjustment for CY 2025. This approach of applying half of the amount proposed for the permanent adjustment is aligned with the approach finalized in the CY 2023 HH PPS final rule (87 FR 66808) and the CY 2024 HH PPS final rule (88 FR 77697) where CMS finalized half of the remaining permanent adjustment, as indicated by the most recently available claims data. However, again, we note the permanent adjustment to account for actual behavior changes in CYs 2020 through 2023, should be -3.95 percent, which includes the remaining ‘‘half’’ from the CY 2024 HH PPS final rule, and the additional adjustment based on CY 2023 data. Therefore, applying a -1.975 percent permanent adjustment to the CY 2025 30-day payment rate would not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures during those years. We will have to account for that difference, and any other potential adjustments needed to the base payment rate, to account for behavior change based on data analysis in future rulemaking. CMS did not propose to adjust the CY 2025 base payment rate using our temporary adjustment authority, as section 1895(b)(3)(D)(iii) of the Act allows any adjustment to be made in a time and manner deemed appropriate by the Secretary. However, we remind readers that without the full permanent adjustment (-3.95 percent) in effect, the total temporary dollar amount will continue to increase until the full permanent adjustment is implemented.

D. 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. 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.E.4.c. of this final 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 will 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 will 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 will 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 will be minimized since the impact will 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 will 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 proposed to update the LUPA thresholds using CY 2023 home health claims utilization data (using more complete CY 2023 claims data as of July 11, 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 and a total of eight case-mix groups have a decline in their LUPA threshold of a single visit. 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 can be found in the CY 2025 HH PPS proposed rule (89 FR 55349). We solicited public comment on the proposed updates to the LUPA thresholds for CY 2025.

Comment: All commenters expressed support for the updated LUPA thresholds and recognized that this adjustment helps align payments more closely with evolving care delivery and improves payment accuracy.

Response: We thank the commenters for their support.

Final Decision: We are finalizing the proposal to update the LUPA thresholds for CY 2025 using CY 2023 claims data (as of July 11, 2024). The final 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 7 and is also available on the HHA Center webpage, located at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.

2. 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 proposed 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 webpage, located at https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive, provides a more detailed explanation as to the construction of the functional impairment levels using the OASIS items. We proposed to use the same methodology previously finalized to update the functional impairment levels for CY 2025. The final updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2025 are listed in tables 7 and 8, respectively.

TABLE 7: FINAL 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**	**2.4%**
	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 July 11, 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 8: FINAL 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 July 11, 2024.

We solicited public comment on the updates to functional points and the functional impairment levels by clinical group.

Comment: Several commenters opposed the proposed updates to the CY 2025 functional impairment points and levels. These commenters contend that the assignment of functional impairment levels appears arbitrary and requested that CMS refrain from making additional changes to the functional scoring system that would affect level assignments until the impact of CY 2024 updates is fully understood. Several commenters expressed concerns that the proposed functional impairment levels may not accurately reflect the actual functional status of home health patients, particularly those with complex or higher-acuity conditions. Specifically, they stated that patients with significant needs for assistance with activities of daily living may not be adequately represented within the proposed levels, potentially leading to a misalignment between the resources required to provide care and the associated payment structure. Additionally, commenters noted that the agency's proposed recalibration for CY 2025 does not sufficiently account for what the commenters say is a fact that patients entering home health care post-COVID-19 pandemic are, on average, more impaired than they were prior to the pandemic. Commenters stated that they believe this marks the fourth consecutive year in which changes to functional item scoring have been finalized without fully considering the impacts of the changes implemented in the previous year (that is, CY 2024 changes for CY 2025 rulemaking). Commenters requested that CMS delay finalizing any updates to the functional domain methodology until CY 2026, when post-pandemic data from 2024 can be fully analyzed to assess the appropriateness of further modifications.

Response: We appreciate the commenters' recommendations. However, we maintain that annual recalibration is essential to ensure the most accurate and current assessment of the relationship between resource use and functional points, functional threshold levels, comorbidities, utilization thresholds, and case-mix weights. As such, we do not agree with delaying updates to the functional impairment points and levels for CY 2025. We continue to believe that using the most up-to-date data to revise functional impairment levels is critical to ensuring that all variables used in the case-mix adjustment process align with the actual costs of

delivering home health services. We would also like to remind commenters that the functional impairment levels are structured so that approximately one-third of periods within each clinical group are assigned to low, medium, and high categories, ensuring that the case-mix system appropriately reflects differences in functional impairment. This classification of functional impairment into low, medium, and high levels has been a fundamental component of the HH PPS since its implementation. The previous HH PPS grouped home health episodes using functional scores based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low functional score, a third of episodes classified as medium functional score, and a third of episodes classified as high functional score. Likewise, the PDGM groups home health periods of care using functional impairment scores based on functional OASIS items with similar resource use and has three levels of functional impairment severity: low, medium, and high. However, the PDGM differs from the previous HH PPS functional variable, in that the three functional impairment level thresholds in the PDGM vary between the clinical groups. As such, the PDGM functional impairment structure accounts for patient characteristics within each clinical group that are associated with increased resource use due to functional impairment. This ensures that payment is more accurately aligned with patient characteristics, including beneficiaries who have greater need with activities of daily living (ADLs) and who are more functionally impaired. Regardless of whether patients entering home health are more impaired due to the post-COVID environment or any other influence, the functional levels capture the relationship between functional status as indicated on the OASIS with resource use captured on claims. As such, updating the functional levels would specifically capture any increase in functional impairment and any increase in resource use associated with ADLs.

Final Decision: We are finalizing the functional points and functional impairment level updates for CY 2025 as proposed, using updated CY 2023 claims data (as of July 11, 2024).

3. 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 will 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 proposed 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.

For CY 2025, we proposed to update the comorbidity subgroups to include 22 low comorbidity adjustment subgroups and 97 high comorbidity adjustment interaction subgroups. The proposed CY 2025 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments was included in the CY 2025 HH PPS proposed rule (89 FR 55340).

We invited comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2025.

Using more updated claims data, for CY 2025 there are 22 low comorbidity subgroups, and 94 high comorbidity subgroups as shown in tables 9 and 10.

TABLE 9: 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 July 11, 2024.

TABLE 10: 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
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

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
19	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
20	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
21	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
22	Circulatory 10	Varicose Veins and Lymphedema	Circulatory 4	#N/A
23	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
24	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
25	Circulatory 10	Varicose Veins and Lymphedema	Heart 11	Heart Failure
26	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 3	Joint Pain
27	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
28	Circulatory 10	Varicose Veins and Lymphedema	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
29	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
30	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Gastrointestinal 2	Intestinal Obstruction and Ileus
31	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
32	Circulatory 4	Hypertensive Chronic Kidney Disease	Circulatory 9	Other Venous Embolism and Thrombosis
33	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
35	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
36	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
37	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
38	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
39	Endocrine 1	Hypothyroidism	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
40	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
41	Endocrine 1	Hypothyroidism	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
42	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
43	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
44	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
45	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
46	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
48	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
49	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
50	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
51	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
52	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
53	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
54	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
55	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
56	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
57	Heart 11	Heart Failure	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
58	Heart 11	Heart Failure	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
59	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
60	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
61	Heart 12	Other Heart Diseases	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
62	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
63	Heart 5	Atherosclerotic Heart Disease with Angina	Neurological 10	Diabetes with neuropathy
64	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
65	Heart 9	Valve Disorders	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
66	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
67	Infectious 1	C-diff, MRSA, E-coli	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
68	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
69	Musculoskeletal 3	Joint Pain	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
70	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
71	Musculoskeletal 3	Joint Pain	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
72	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
73	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
74	Neurological 10	Diabetes with neuropathy	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
75	Neurological 10	Diabetes with neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
76	Neurological 10	Diabetes with neuropathy	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
77	Neurological 12	Nondiabetic neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
78	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
79	Neurological 4	Alzheimer’s disease and related dementias	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
80	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
81	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
82	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
83	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
84	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
85	Renal 1	Chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
86	Renal 1	Chronic kidney disease and ESRD	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
87	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
88	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
89	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
91	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
92	Respiratory 9	Respiratory Failure and Atelectasis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
93	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
94	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 July 11, 2024.

Comment: Several commenters expressed support for the proposed low and high comorbidity adjustments, particularly those pertaining to low comorbidity adjustments for diagnoses such as diabetes and endocrine disorders. Commenters stated these adjustments will result in more accurate payment, reflecting the resources required to effectively manage patients with these conditions. Additionally, commenters indicated that the proposed changes to the comorbidity subgroups align with the stated objective of ensuring that payments more accurately reflect the actual costs of providing care.

Response: We thank commenters for their support.

Comment: A commenter expressed concern that the COVID-19 diagnosis was excluded from the comorbidity grouping list, despite its continued impact on elderly and high-risk patients. Another commenter also pointed out that *Circulatory 1* (nutritional anemias) are grouped with *Skin 3* (non-pressure ulcers), but not with *Skin 4* (pressure ulcers). Furthermore, *Circulatory 2* (hemolytic, aplastic, and other anemias) are no longer grouped with either *Skin 3* or *Skin 4*. Commenters raised concerns as to why certain anemias are recognized as having an impact on some ulcer types but not others. They also stated that the same principle should apply to *Circulatory 1* and *Circulatory 2*, as anemias included in *Circulatory 2* are likely to result in greater complications, such as compromised strength and skin integrity, than those in *Circulatory 1*.

Response: We appreciate commenters' thorough review of these groupings. As outlined in the CY 2020 final rule with comment period (84 FR 60510) and further detailed in the technical report "Overview of the Home Health Groupings Model", the Home Health Specific Comorbidity List stems from the principles of patient assessment by providers, as well as the evaluation of body systems and their associated diseases, conditions, and injuries. This framework was used to develop condition categories that identify clinically relevant relationships tied to increased resource use.

We acknowledge the complexity and breadth of clinical conditions, comorbidities, and their interactions within the Medicare home health population. However, we remind commenters that only subgroups of diagnoses representing more than 0.1% of periods of care, and demonstrating at least the median resource use, qualify for a low comorbidity adjustment. For example, in reference to the commenter's concern regarding the grouping of *Circulatory 1* (nutritional anemias) with *Skin* 3 (non-pressure ulcers), and the exclusion of *Circulatory 2* (hemolytic, aplastic, and other anemias) from both *Skin 3* and *Skin 4* groupings, these categorizations are driven by data reflecting resource utilization patterns. If the anemias in *Circulatory 2* do not demonstrate the requisite median resource use in relation to specific ulcer types, such as *Skin 4* (pressure ulcers), they would not qualify for inclusion in the comorbidity list. This explains why certain anemias appear in the comorbidity list for one ulcer category but not for another despite clinical similarities or the potential for greater clinical complications like compromised strength and skin integrity. This methodology for determining statistical significance was detailed in the CY 2020 final rule with comment period (84 FR 60510). It is based on the understanding that the aggregate number of comorbidities within the population forms the standard for payment purposes. While we expect HHAs to report all secondary diagnoses that impact care planning, nevertheless it is important to note that certain comorbidity subgroups included in the Home Health Specific List may not meet the criteria for a payment adjustment.

Final Decision: We are finalizing the updated comorbidity adjustment subgroups and the high comorbidity adjustment interactions using CY 2023 home health data. For CY 2025, the final updated comorbidity adjustment subgroups include 22 low comorbidity adjustment subgroups as identified in table 9 and 94 high comorbidity adjustment interaction subgroups as identified in table 10. The final 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 webpage at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

4. 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). We included the proposed case-mix weights in table 25 of the proposed rule (89 FR 55351). In this final rule, we updated these case-mix weights with claims data as of July 11, 2024, as shown in table 11. These data are the most current and complete data available at the time of rulemaking.

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 25 of the proposed rule 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 11 shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

TABLE 11: 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	$146.94	1.2%	0.0897
MMTA - Other - High Functional	$308.86	1.3%	0.1886
MMTA - Surgical Aftercare - Low Functional	-$43.59	1.2%	-0.0266
MMTA - Surgical Aftercare - Medium Functional	$150.02	1.2%	0.0916
MMTA - Surgical Aftercare - High Functional	$358.75	1.1%	0.2190
MMTA - Cardiac and Circulatory - Low Functional	-$14.06	6.1%	-0.0086
MMTA - Cardiac and Circulatory - Medium Functional	$127.58	5.9%	0.0779
MMTA - Cardiac and Circulatory - High Functional	$318.73	6.1%	0.1946
MMTA - Endocrine - Low Functional	$439.39	2.6%	0.2683
MMTA - Endocrine - Medium Functional	$556.03	2.3%	0.3395
MMTA - Endocrine - High Functional	$670.82	2.2%	0.4096
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$42.85	1.7%	-0.0262
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$153.47	1.7%	0.0937
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$298.89	1.7%	0.1825
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	-$18.14	1.6%	-0.0111
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium Functional	$145.98	1.6%	0.0891
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$359.62	1.5%	0.2196
MMTA - Respiratory - Low Functional	-$0.07	2.8%	0.0000
MMTA - Respiratory - Medium Functional	$159.83	2.2%	0.0976
MMTA - Respiratory - High Functional	$330.28	2.4%	0.2017
Behavioral Health - Low Functional	-$75.32	0.8%	-0.0460
Behavioral Health - Medium Functional	$119.39	0.7%	0.0729
Behavioral Health - High Functional	$282.54	0.7%	0.1725
Complex - Low Functional	-$76.08	0.9%	-0.0465
Complex - Medium Functional	$137.96	0.9%	0.0842
Complex - High Functional	$112.02	0.9%	0.0684
MS Rehab - Low Functional	$58.17	7.3%	0.0355
MS Rehab - Medium Functional	$193.69	7.2%	0.1183
MS Rehab - High Functional	$422.68	7.1%	0.2581
Neuro - Low Functional	$200.73	3.2%	0.1226
Neuro - Medium Functional	$383.59	3.2%	0.2342
Neuro - High Functional	$612.76	3.2%	0.3741
Wound - Low Functional	$599.94	5.3%	0.3663
Wound - Medium Functional	$756.04	4.2%	0.4616
Wound - High Functional	$948.28	4.8%	0.5790

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	-$570.18	63.3%	-0.3481
Institutional - Early	$339.53	19.2%	0.2073
Institutional - Late	$212.19	6.1%	0.1296
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no interaction from interaction list	$101.92	58.5%	0.0622
Comorbidity Adjustment - Has at least one interaction from interaction list	$346.45	16.0%	0.2115
Constant	$1,504.69		
Average Resource Use	$1,637.79		
Number of 30-day Periods	7,557,273		
Adjusted R-Squared	0.3144		

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW July 11, 2024.

The final updated case-mix weights for CY 2025 are listed in table 12 and will also be posted on the HHA Center webpage[10] upon display of this final rule.

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

TABLE 12: 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	1.0912	4
1FC21	Behavioral Health - High	Early - Community	1	1.1535	4
1FC31	Behavioral Health - High	Early - Community	2	1.3028	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.2986	3
2FC21	Behavioral Health - High	Early - Institutional	1	1.3608	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.5101	4
3FC11	Behavioral Health - High	Late - Community	0	0.7431	2
3FC21	Behavioral Health - High	Late - Community	1	0.8053	2
3FC31	Behavioral Health - High	Late - Community	2	0.9546	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.2208	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2830	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4323	4
1FA11	Behavioral Health - Low	Early - Community	0	0.8727	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9350	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0843	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0801	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1423	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2916	3
3FA11	Behavioral Health - Low	Late - Community	0	0.5246	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5868	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7361	2
4FA11	Behavioral Health - Low	Late - Institutional	0	1.0023	2
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0645	3
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2138	2
1FB11	Behavioral Health - Medium	Early - Community	0	0.9916	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0539	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2032	4
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.1989	3
2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2612	4
2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4105	4
3FB11	Behavioral Health - Medium	Late - Community	0	0.6435	2
3FB21	Behavioral Health - Medium	Late - Community	1	0.7057	2
3FB31	Behavioral Health - Medium	Late - Community	2	0.8550	2
4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1212	3
4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1834	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)
4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3327	3
1DC11	Complex - High	Early - Community	0	0.9871	2
1DC21	Complex - High	Early - Community	1	1.0494	2
1DC31	Complex - High	Early - Community	2	1.1987	2
2DC11	Complex - High	Early - Institutional	0	1.1944	3
2DC21	Complex - High	Early - Institutional	1	1.2567	3
2DC31	Complex - High	Early - Institutional	2	1.4060	3
3DC11	Complex - High	Late - Community	0	0.6390	2
3DC21	Complex - High	Late - Community	1	0.7012	2
3DC31	Complex - High	Late - Community	2	0.8505	2
4DC11	Complex - High	Late - Institutional	0	1.1167	2
4DC21	Complex - High	Late - Institutional	1	1.1789	2
4DC31	Complex - High	Late - Institutional	2	1.3282	2
1DA11	Complex - Low	Early - Community	0	0.8723	2
1DA21	Complex - Low	Early - Community	1	0.9345	2
1DA31	Complex - Low	Early - Community	2	1.0838	2
2DA11	Complex - Low	Early - Institutional	0	1.0796	3
2DA21	Complex - Low	Early - Institutional	1	1.1418	3
2DA31	Complex - Low	Early - Institutional	2	1.2911	3
3DA11	Complex - Low	Late - Community	0	0.5241	2
3DA21	Complex - Low	Late - Community	1	0.5864	2
3DA31	Complex - Low	Late - Community	2	0.7357	2
4DA11	Complex - Low	Late - Institutional	0	1.0018	2
4DA21	Complex - Low	Late - Institutional	1	1.0641	2
4DA31	Complex - Low	Late - Institutional	2	1.2134	3
1DB11	Complex - Medium	Early - Community	0	1.0030	2
1DB21	Complex - Medium	Early - Community	1	1.0652	2
1DB31	Complex - Medium	Early - Community	2	1.2145	2
2DB11	Complex - Medium	Early - Institutional	0	1.2103	3
2DB21	Complex - Medium	Early - Institutional	1	1.2725	3
2DB31	Complex - Medium	Early - Institutional	2	1.4218	4
3DB11	Complex - Medium	Late - Community	0	0.6548	2
3DB21	Complex - Medium	Late - Community	1	0.7171	2
3DB31	Complex - Medium	Late - Community	2	0.8664	2
4DB11	Complex - Medium	Late - Institutional	0	1.1325	3
4DB21	Complex - Medium	Late - Institutional	1	1.1948	3
4DB31	Complex - Medium	Late - Institutional	2	1.3441	3
1HC11	MMTA - Cardiac - High	Early - Community	0	1.1133	4

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)
1HC21	MMTA - Cardiac - High	Early - Community	1	1.1756	4
1HC31	MMTA - Cardiac - High	Early - Community	2	1.3249	4
2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3207	4
2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3829	4
2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5322	4
3HC11	MMTA - Cardiac - High	Late - Community	0	0.7652	2
3HC21	MMTA - Cardiac - High	Late - Community	1	0.8274	2
3HC31	MMTA - Cardiac - High	Late - Community	2	0.9767	3
4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2429	3
4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.3051	3
4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4544	4
1HA11	MMTA - Cardiac - Low	Early - Community	0	0.9102	4
1HA21	MMTA - Cardiac - Low	Early - Community	1	0.9724	4
1HA31	MMTA - Cardiac - Low	Early - Community	2	1.1217	3
2HA11	MMTA - Cardiac - Low	Early - Institutional	0	1.1175	3
2HA21	MMTA - Cardiac - Low	Early - Institutional	1	1.1797	4
2HA31	MMTA - Cardiac - Low	Early - Institutional	2	1.3290	4
3HA11	MMTA - Cardiac - Low	Late - Community	0	0.5620	2
3HA21	MMTA - Cardiac - Low	Late - Community	1	0.6242	2
3HA31	MMTA - Cardiac - Low	Late - Community	2	0.7735	2
4HA11	MMTA - Cardiac - Low	Late - Institutional	0	1.0397	3
4HA21	MMTA - Cardiac - Low	Late - Institutional	1	1.1019	3
4HA31	MMTA - Cardiac - Low	Late - Institutional	2	1.2512	3
1HB11	MMTA - Cardiac - Medium	Early - Community	0	0.9966	4
1HB21	MMTA - Cardiac - Medium	Early - Community	1	1.0589	4
1HB31	MMTA - Cardiac - Medium	Early - Community	2	1.2082	4
2HB11	MMTA - Cardiac - Medium	Early - Institutional	0	1.2039	4
2HB21	MMTA - Cardiac - Medium	Early - Institutional	1	1.2662	4
2HB31	MMTA - Cardiac - Medium	Early - Institutional	2	1.4155	4
3HB11	MMTA - Cardiac - Medium	Late - Community	0	0.6485	2
3HB21	MMTA - Cardiac - Medium	Late - Community	1	0.7107	2
3HB31	MMTA - Cardiac - Medium	Late - Community	2	0.8600	2
4HB11	MMTA - Cardiac - Medium	Late - Institutional	0	1.1262	3
4HB21	MMTA - Cardiac - Medium	Late - Institutional	1	1.1884	3
4HB31	MMTA - Cardiac - Medium	Late - Institutional	2	1.3377	3
1IC11	MMTA - Endocrine - High	Early - Community	0	1.3283	4
1IC21	MMTA - Endocrine - High	Early - Community	1	1.3906	4
1IC31	MMTA - Endocrine - High	Early - Community	2	1.5399	4

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)
2IC11	MMTA - Endocrine - High	Early - Institutional	0	1.5356	4
2IC21	MMTA - Endocrine - High	Early - Institutional	1	1.5979	4
2IC31	MMTA - Endocrine - High	Early - Institutional	2	1.7472	4
3IC11	MMTA - Endocrine - High	Late - Community	0	0.9802	3
3IC21	MMTA - Endocrine - High	Late - Community	1	1.0424	3
3IC31	MMTA - Endocrine - High	Late - Community	2	1.1917	3
4IC11	MMTA - Endocrine - High	Late - Institutional	0	1.4579	4
4IC21	MMTA - Endocrine - High	Late - Institutional	1	1.5201	4
4IC31	MMTA - Endocrine - High	Late - Institutional	2	1.6694	4
1IA11	MMTA - Endocrine - Low	Early - Community	0	1.1870	4
1IA21	MMTA - Endocrine - Low	Early - Community	1	1.2492	4
1IA31	MMTA - Endocrine - Low	Early - Community	2	1.3986	4
2IA11	MMTA - Endocrine - Low	Early - Institutional	0	1.3943	3
2IA21	MMTA - Endocrine - Low	Early - Institutional	1	1.4566	4
2IA31	MMTA - Endocrine - Low	Early - Institutional	2	1.6059	4
3IA11	MMTA - Endocrine - Low	Late - Community	0	0.8389	3
3IA21	MMTA - Endocrine - Low	Late - Community	1	0.9011	3
3IA31	MMTA - Endocrine - Low	Late - Community	2	1.0504	3
4IA11	MMTA - Endocrine - Low	Late - Institutional	0	1.3166	4
4IA21	MMTA - Endocrine - Low	Late - Institutional	1	1.3788	3
4IA31	MMTA - Endocrine - Low	Late - Institutional	2	1.5281	4
1IB11	MMTA - Endocrine - Medium	Early - Community	0	1.2582	4
1IB21	MMTA - Endocrine - Medium	Early - Community	1	1.3205	4
1IB31	MMTA - Endocrine - Medium	Early - Community	2	1.4698	4
2IB11	MMTA - Endocrine - Medium	Early - Institutional	0	1.4655	4
2IB21	MMTA - Endocrine - Medium	Early - Institutional	1	1.5278	4
2IB31	MMTA - Endocrine - Medium	Early - Institutional	2	1.6771	4
3IB11	MMTA - Endocrine - Medium	Late - Community	0	0.9101	3
3IB21	MMTA - Endocrine - Medium	Late - Community	1	0.9723	3
3IB31	MMTA - Endocrine - Medium	Late - Community	2	1.1216	3
4IB11	MMTA - Endocrine - Medium	Late - Institutional	0	1.3878	4
4IB21	MMTA - Endocrine - Medium	Late - Institutional	1	1.4500	4
4IB31	MMTA - Endocrine - Medium	Late - Institutional	2	1.5993	4
1JC11	MMTA - GI/GU - High	Early - Community	0	1.1012	3
1JC21	MMTA - GI/GU - High	Early - Community	1	1.1635	3
1JC31	MMTA - GI/GU - High	Early - Community	2	1.3128	2
2JC11	MMTA - GI/GU - High	Early - Institutional	0	1.3085	4
2JC21	MMTA - GI/GU - High	Early - Institutional	1	1.3708	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)
2JC31	MMTA - GI/GU - High	Early - Institutional	2	1.5201	3
3JC11	MMTA - GI/GU - High	Late - Community	0	0.7531	2
3JC21	MMTA - GI/GU - High	Late - Community	1	0.8153	2
3JC31	MMTA - GI/GU - High	Late - Community	2	0.9646	2
4JC11	MMTA - GI/GU - High	Late - Institutional	0	1.2308	3
4JC21	MMTA - GI/GU - High	Late - Institutional	1	1.2930	3
4JC31	MMTA - GI/GU - High	Late - Institutional	2	1.4423	3
1JA11	MMTA - GI/GU - Low	Early - Community	0	0.8926	2
1JA21	MMTA - GI/GU - Low	Early - Community	1	0.9548	2
1JA31	MMTA - GI/GU - Low	Early - Community	2	1.1041	2
2JA11	MMTA - GI/GU - Low	Early - Institutional	0	1.0999	3
2JA21	MMTA - GI/GU - Low	Early - Institutional	1	1.1621	3
2JA31	MMTA - GI/GU - Low	Early - Institutional	2	1.3114	3
3JA11	MMTA - GI/GU - Low	Late - Community	0	0.5444	2
3JA21	MMTA - GI/GU - Low	Late - Community	1	0.6067	2
3JA31	MMTA - GI/GU - Low	Late - Community	2	0.7560	2
4JA11	MMTA - GI/GU - Low	Late - Institutional	0	1.0221	3
4JA21	MMTA - GI/GU - Low	Late - Institutional	1	1.0844	3
4JA31	MMTA - GI/GU - Low	Late - Institutional	2	1.2337	3
1JB11	MMTA - GI/GU - Medium	Early - Community	0	1.0124	3
1JB21	MMTA - GI/GU - Medium	Early - Community	1	1.0747	3
1JB31	MMTA - GI/GU - Medium	Early - Community	2	1.2240	2
2JB11	MMTA - GI/GU - Medium	Early - Institutional	0	1.2197	3
2JB21	MMTA - GI/GU - Medium	Early - Institutional	1	1.2820	4
2JB31	MMTA - GI/GU - Medium	Early - Institutional	2	1.4313	4
3JB11	MMTA - GI/GU - Medium	Late - Community	0	0.6643	2
3JB21	MMTA - GI/GU - Medium	Late - Community	1	0.7265	2
3JB31	MMTA - GI/GU - Medium	Late - Community	2	0.8758	2
4JB11	MMTA - GI/GU - Medium	Late - Institutional	0	1.1420	3
4JB21	MMTA - GI/GU - Medium	Late - Institutional	1	1.2042	3
4JB31	MMTA - GI/GU - Medium	Late - Institutional	2	1.3535	3
1KC11	MMTA - Infectious - High	Early - Community	0	1.1383	2
1KC21	MMTA - Infectious - High	Early - Community	1	1.2005	2
1KC31	MMTA - Infectious - High	Early - Community	2	1.3498	2
2KC11	MMTA - Infectious - High	Early - Institutional	0	1.3456	3
2KC21	MMTA - Infectious - High	Early - Institutional	1	1.4079	3
2KC31	MMTA - Infectious - High	Early - Institutional	2	1.5572	3
3KC11	MMTA - Infectious - High	Late - Community	0	0.7902	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)
3KC21	MMTA - Infectious - High	Late - Community	1	0.8524	2
3KC31	MMTA - Infectious - High	Late - Community	2	1.0017	2
4KC11	MMTA - Infectious - High	Late - Institutional	0	1.2679	3
4KC21	MMTA - Infectious - High	Late - Institutional	1	1.3301	3
4KC31	MMTA - Infectious - High	Late - Institutional	2	1.4794	3
1KA11	MMTA - Infectious - Low	Early - Community	0	0.9077	2
1KA21	MMTA - Infectious - Low	Early - Community	1	0.9699	2
1KA31	MMTA - Infectious - Low	Early - Community	2	1.1192	2
2KA11	MMTA - Infectious - Low	Early - Institutional	0	1.1150	3
2KA21	MMTA - Infectious - Low	Early - Institutional	1	1.1772	3
2KA31	MMTA - Infectious - Low	Early - Institutional	2	1.3265	3
3KA11	MMTA - Infectious - Low	Late - Community	0	0.5595	2
3KA21	MMTA - Infectious - Low	Late - Community	1	0.6217	2
3KA31	MMTA - Infectious - Low	Late - Community	2	0.7711	2
4KA11	MMTA - Infectious - Low	Late - Institutional	0	1.0372	3
4KA21	MMTA - Infectious - Low	Late - Institutional	1	1.0994	3
4KA31	MMTA - Infectious - Low	Late - Institutional	2	1.2487	3
1KB11	MMTA - Infectious - Medium	Early - Community	0	1.0079	3
1KB21	MMTA - Infectious - Medium	Early - Community	1	1.0701	2
1KB31	MMTA - Infectious - Medium	Early - Community	2	1.2194	2
2KB11	MMTA - Infectious - Medium	Early - Institutional	0	1.2152	3
2KB21	MMTA - Infectious - Medium	Early - Institutional	1	1.2774	3
2KB31	MMTA - Infectious - Medium	Early - Institutional	2	1.4267	3
3KB11	MMTA - Infectious - Medium	Late - Community	0	0.6597	2
3KB21	MMTA - Infectious - Medium	Late - Community	1	0.7220	2
3KB31	MMTA - Infectious - Medium	Late - Community	2	0.8713	2
4KB11	MMTA - Infectious - Medium	Late - Institutional	0	1.1374	3
4KB21	MMTA - Infectious - Medium	Late - Institutional	1	1.1997	3
4KB31	MMTA - Infectious - Medium	Late - Institutional	2	1.3490	3
1AC11	MMTA - Other - High	Early - Community	0	1.1073	4
1AC21	MMTA - Other - High	Early - Community	1	1.1695	4
1AC31	MMTA - Other - High	Early - Community	2	1.3189	3
2AC11	MMTA - Other - High	Early - Institutional	0	1.3146	4
2AC21	MMTA - Other - High	Early - Institutional	1	1.3769	4
2AC31	MMTA - Other - High	Early - Institutional	2	1.5262	4
3AC11	MMTA - Other - High	Late - Community	0	0.7592	2
3AC21	MMTA - Other - High	Late - Community	1	0.8214	2
3AC31	MMTA - Other - High	Late - Community	2	0.9707	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)
4AC11	MMTA - Other - High	Late - Institutional	0	1.2369	3
4AC21	MMTA - Other - High	Late - Institutional	1	1.2991	3
4AC31	MMTA - Other - High	Late - Institutional	2	1.4484	3
1AA11	MMTA - Other - Low	Early - Community	0	0.9187	3
1AA21	MMTA - Other - Low	Early - Community	1	0.9810	3
1AA31	MMTA - Other - Low	Early - Community	2	1.1303	4
2AA11	MMTA - Other - Low	Early - Institutional	0	1.1260	3
2AA21	MMTA - Other - Low	Early - Institutional	1	1.1883	3
2AA31	MMTA - Other - Low	Early - Institutional	2	1.3376	3
3AA11	MMTA - Other - Low	Late - Community	0	0.5706	2
3AA21	MMTA - Other - Low	Late - Community	1	0.6328	2
3AA31	MMTA - Other - Low	Late - Community	2	0.7821	2
4AA11	MMTA - Other - Low	Late - Institutional	0	1.0483	3
4AA21	MMTA - Other - Low	Late - Institutional	1	1.1105	3
4AA31	MMTA - Other - Low	Late - Institutional	2	1.2598	3
1AB11	MMTA - Other - Medium	Early - Community	0	1.0085	4
1AB21	MMTA - Other - Medium	Early - Community	1	1.0707	4
1AB31	MMTA - Other - Medium	Early - Community	2	1.2200	3
2AB11	MMTA - Other - Medium	Early - Institutional	0	1.2158	4
2AB21	MMTA - Other - Medium	Early - Institutional	1	1.2780	4
2AB31	MMTA - Other - Medium	Early - Institutional	2	1.4273	4
3AB11	MMTA - Other - Medium	Late - Community	0	0.6603	2
3AB21	MMTA - Other - Medium	Late - Community	1	0.7225	2
3AB31	MMTA - Other - Medium	Late - Community	2	0.8718	2
4AB11	MMTA - Other - Medium	Late - Institutional	0	1.1380	3
4AB21	MMTA - Other - Medium	Late - Institutional	1	1.2002	3
4AB31	MMTA - Other - Medium	Late - Institutional	2	1.3495	4
1LC11	MMTA - Respiratory - High	Early - Community	0	1.1204	4
1LC21	MMTA - Respiratory - High	Early - Community	1	1.1826	3
1LC31	MMTA - Respiratory - High	Early - Community	2	1.3319	3
2LC11	MMTA - Respiratory - High	Early - Institutional	0	1.3277	4
2LC21	MMTA - Respiratory - High	Early - Institutional	1	1.3899	4
2LC31	MMTA - Respiratory - High	Early - Institutional	2	1.5392	4
3LC11	MMTA - Respiratory - High	Late - Community	0	0.7723	2
3LC21	MMTA - Respiratory - High	Late - Community	1	0.8345	2
3LC31	MMTA - Respiratory - High	Late - Community	2	0.9838	2
4LC11	MMTA - Respiratory - High	Late - Institutional	0	1.2499	3
4LC21	MMTA - Respiratory - High	Late - Institutional	1	1.3122	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)
4LC31	MMTA - Respiratory - High	Late - Institutional	2	1.4615	3
1LA11	MMTA - Respiratory - Low	Early - Community	0	0.9187	3
1LA21	MMTA - Respiratory - Low	Early - Community	1	0.9809	3
1LA31	MMTA - Respiratory - Low	Early - Community	2	1.1302	3
2LA11	MMTA - Respiratory - Low	Early - Institutional	0	1.1260	3
2LA21	MMTA - Respiratory - Low	Early - Institutional	1	1.1882	3
2LA31	MMTA - Respiratory - Low	Early - Institutional	2	1.3375	4
3LA11	MMTA - Respiratory - Low	Late - Community	0	0.5705	2
3LA21	MMTA - Respiratory - Low	Late - Community	1	0.6328	2
3LA31	MMTA - Respiratory - Low	Late - Community	2	0.7821	2
4LA11	MMTA - Respiratory - Low	Late - Institutional	0	1.0482	3
4LA21	MMTA - Respiratory - Low	Late - Institutional	1	1.1105	3
4LA31	MMTA - Respiratory - Low	Late - Institutional	2	1.2598	3
1LB11	MMTA - Respiratory - Medium	Early - Community	0	1.0163	4
1LB21	MMTA - Respiratory - Medium	Early - Community	1	1.0786	3
1LB31	MMTA - Respiratory - Medium	Early - Community	2	1.2279	3
2LB11	MMTA - Respiratory - Medium	Early - Institutional	0	1.2236	4
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1	1.2859	4
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2	1.4352	4
3LB11	MMTA - Respiratory - Medium	Late - Community	0	0.6682	2
3LB21	MMTA - Respiratory - Medium	Late - Community	1	0.7304	2
3LB31	MMTA - Respiratory - Medium	Late - Community	2	0.8797	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0	1.1459	3
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1	1.2081	3
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2	1.3574	3
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0	1.1378	3
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1	1.2000	3
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2	1.3493	3
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0	1.3451	4
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1	1.4073	4
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2	1.5566	4
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0	0.7896	2
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1	0.8519	2
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2	1.0012	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0	1.2673	3
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1	1.3296	3
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2	1.4789	4
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0	0.8921	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)
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1	0.9544	2
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2	1.1037	2
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0	1.0994	3
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1	1.1617	3
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2	1.3110	3
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0	0.5440	2
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1	0.6062	2
3GA31	MMTA - Surgical Aftercare - Low	Late - Community	2	0.7555	2
4GA11	MMTA - Surgical Aftercare - Low	Late - Institutional	0	1.0217	2
4GA21	MMTA - Surgical Aftercare - Low	Late - Institutional	1	1.0839	3
4GA31	MMTA - Surgical Aftercare - Low	Late - Institutional	2	1.2332	3
1GB11	MMTA - Surgical Aftercare - Medium	Early - Community	0	1.0103	3
1GB21	MMTA - Surgical Aftercare - Medium	Early - Community	1	1.0726	3
1GB31	MMTA - Surgical Aftercare - Medium	Early - Community	2	1.2219	3
2GB11	MMTA - Surgical Aftercare - Medium	Early - Institutional	0	1.2176	3
2GB21	MMTA - Surgical Aftercare - Medium	Early - Institutional	1	1.2799	4
2GB31	MMTA - Surgical Aftercare - Medium	Early - Institutional	2	1.4292	4
3GB11	MMTA - Surgical Aftercare - Medium	Late - Community	0	0.6622	2
3GB21	MMTA - Surgical Aftercare - Medium	Late - Community	1	0.7244	2
3GB31	MMTA - Surgical Aftercare - Medium	Late - Community	2	0.8737	2
4GB11	MMTA - Surgical Aftercare - Medium	Late - Institutional	0	1.1399	3
4GB21	MMTA - Surgical Aftercare - Medium	Late - Institutional	1	1.2021	3
4GB31	MMTA - Surgical Aftercare - Medium	Late - Institutional	2	1.3514	4
1EC11	MS Rehab - High	Early - Community	0	1.1768	4
1EC21	MS Rehab - High	Early - Community	1	1.2390	4
1EC31	MS Rehab - High	Early - Community	2	1.3884	4
2EC11	MS Rehab - High	Early - Institutional	0	1.3841	5
2EC21	MS Rehab - High	Early - Institutional	1	1.4464	5
2EC31	MS Rehab - High	Early - Institutional	2	1.5957	5
3EC11	MS Rehab - High	Late - Community	0	0.8287	2
3EC21	MS Rehab - High	Late - Community	1	0.8909	2
3EC31	MS Rehab - High	Late - Community	2	1.0402	3
4EC11	MS Rehab - High	Late - Institutional	0	1.3064	4
4EC21	MS Rehab - High	Late - Institutional	1	1.3686	4
4EC31	MS Rehab - High	Late - Institutional	2	1.5179	4
1EA11	MS Rehab - Low	Early - Community	0	0.9543	4
1EA21	MS Rehab - Low	Early - Community	1	1.0165	4
1EA31	MS Rehab - Low	Early - Community	2	1.1658	4

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)
2EA11	MS Rehab - Low	Early - Institutional	0	1.1616	4
2EA21	MS Rehab - Low	Early - Institutional	1	1.2238	5
2EA31	MS Rehab - Low	Early - Institutional	2	1.3731	5
3EA11	MS Rehab - Low	Late - Community	0	0.6061	2
3EA21	MS Rehab - Low	Late - Community	1	0.6683	2
3EA31	MS Rehab - Low	Late - Community	2	0.8176	2
4EA11	MS Rehab - Low	Late - Institutional	0	1.0838	4
4EA21	MS Rehab - Low	Late - Institutional	1	1.1460	4
4EA31	MS Rehab - Low	Late - Institutional	2	1.2953	4
1EB11	MS Rehab - Medium	Early - Community	0	1.0370	5
1EB21	MS Rehab - Medium	Early - Community	1	1.0992	5
1EB31	MS Rehab - Medium	Early - Community	2	1.2485	4
2EB11	MS Rehab - Medium	Early - Institutional	0	1.2443	5
2EB21	MS Rehab - Medium	Early - Institutional	1	1.3065	5
2EB31	MS Rehab - Medium	Early - Institutional	2	1.4558	5
3EB11	MS Rehab - Medium	Late - Community	0	0.6889	2
3EB21	MS Rehab - Medium	Late - Community	1	0.7511	2
3EB31	MS Rehab - Medium	Late - Community	2	0.9004	2
4EB11	MS Rehab - Medium	Late - Institutional	0	1.1666	4
4EB21	MS Rehab - Medium	Late - Institutional	1	1.2288	4
4EB31	MS Rehab - Medium	Late - Institutional	2	1.3781	4
1BC11	Neuro - High	Early - Community	0	1.2929	4
1BC21	Neuro - High	Early - Community	1	1.3551	4
1BC31	Neuro - High	Early - Community	2	1.5044	4
2BC11	Neuro - High	Early - Institutional	0	1.5002	5
2BC21	Neuro - High	Early - Institutional	1	1.5624	5
2BC31	Neuro - High	Early - Institutional	2	1.7117	4
3BC11	Neuro - High	Late - Community	0	0.9447	2
3BC21	Neuro - High	Late - Community	1	1.0070	3
3BC31	Neuro - High	Late - Community	2	1.1563	3
4BC11	Neuro - High	Late - Institutional	0	1.4224	4
4BC21	Neuro - High	Late - Institutional	1	1.4847	4
4BC31	Neuro - High	Late - Institutional	2	1.6340	4
1BA11	Neuro - Low	Early - Community	0	1.0413	4
1BA21	Neuro - Low	Early - Community	1	1.1035	4
1BA31	Neuro - Low	Early - Community	2	1.2528	3
2BA11	Neuro - Low	Early - Institutional	0	1.2486	4
2BA21	Neuro - Low	Early - Institutional	1	1.3108	4

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)
2BA31	Neuro - Low	Early - Institutional	2	1.4601	4
3BA11	Neuro - Low	Late - Community	0	0.6932	2
3BA21	Neuro - Low	Late - Community	1	0.7554	2
3BA31	Neuro - Low	Late - Community	2	0.9047	2
4BA11	Neuro - Low	Late - Institutional	0	1.1709	3
4BA21	Neuro - Low	Late - Institutional	1	1.2331	3
4BA31	Neuro - Low	Late - Institutional	2	1.3824	3
1BB11	Neuro - Medium	Early - Community	0	1.1529	4
1BB21	Neuro - Medium	Early - Community	1	1.2152	4
1BB31	Neuro - Medium	Early - Community	2	1.3645	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3603	4
2BB21	Neuro - Medium	Early - Institutional	1	1.4225	5
2BB31	Neuro - Medium	Early - Institutional	2	1.5718	5
3BB11	Neuro - Medium	Late - Community	0	0.8048	2
3BB21	Neuro - Medium	Late - Community	1	0.8670	2
3BB31	Neuro - Medium	Late - Community	2	1.0163	2
4BB11	Neuro - Medium	Late - Institutional	0	1.2825	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3447	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4940	4
1CC11	Wound - High	Early - Community	0	1.4977	4
1CC21	Wound - High	Early - Community	1	1.5600	4
1CC31	Wound - High	Early - Community	2	1.7093	4
2CC11	Wound - High	Early - Institutional	0	1.7050	5
2CC21	Wound - High	Early - Institutional	1	1.7673	4
2CC31	Wound - High	Early - Institutional	2	1.9166	4
3CC11	Wound - High	Late - Community	0	1.1496	3
3CC21	Wound - High	Late - Community	1	1.2118	3
3CC31	Wound - High	Late - Community	2	1.3611	3
4CC11	Wound - High	Late - Institutional	0	1.6273	4
4CC21	Wound - High	Late - Institutional	1	1.6895	4
4CC31	Wound - High	Late - Institutional	2	1.8388	4
1CA11	Wound - Low	Early - Community	0	1.2850	4
1CA21	Wound - Low	Early - Community	1	1.3473	4
1CA31	Wound - Low	Early - Community	2	1.4966	4
2CA11	Wound - Low	Early - Institutional	0	1.4924	4
2CA21	Wound - Low	Early - Institutional	1	1.5546	4
2CA31	Wound - Low	Early - Institutional	2	1.7039	4
3CA11	Wound - Low	Late - Community	0	0.9369	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)
3CA21	Wound - Low	Late - Community	1	0.9991	3
3CA31	Wound - Low	Late - Community	2	1.1484	3
4CA11	Wound - Low	Late - Institutional	0	1.4146	3
4CA21	Wound - Low	Late - Institutional	1	1.4768	4
4CA31	Wound - Low	Late - Institutional	2	1.6261	4
1CB11	Wound - Medium	Early - Community	0	1.3804	4
1CB21	Wound - Medium	Early - Community	1	1.4426	4
1CB31	Wound - Medium	Early - Community	2	1.5919	4
2CB11	Wound - Medium	Early - Institutional	0	1.5877	4
2CB21	Wound - Medium	Early - Institutional	1	1.6499	4
2CB31	Wound - Medium	Early - Institutional	2	1.7992	4
3CB11	Wound - Medium	Late - Community	0	1.0322	3
3CB21	Wound - Medium	Late - Community	1	1.0944	3
3CB31	Wound - Medium	Late - Community	2	1.2438	3
4CB11	Wound - Medium	Late - Institutional	0	1.5099	4
4CB21	Wound - Medium	Late - Institutional	1	1.5721	4
4CB31	Wound - Medium	Late - Institutional	2	1.7214	4

Source: CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on the CCW July 11, 2024.

Changes to the PDGM case-mix weights are implemented in a budget neutral manner by multiplying the CY 2025 national standardized 30-day 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 1.0039.

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

Comment: Several commenters expressed support for the updated case-mix weights using the most current data available for recalibration.

Response: We thank the commenters for their support.

Comment: A few commenters stated that any recalibration should not be budget neutral. They stated this stance is based on several factors, including the increasing acuity of patients, rising operational expenses, growing demand for home health services, and the ongoing labor shortage. Commenters stated that these factors warrant consideration in ensuring adequate payment to align with the current healthcare environment. Specifically, a commenter disagreed with the downgrading of points for toilet transfers and ambulation. While the commenter acknowledged that budget neutrality drives the reallocation of points when others are increased, they expressed concern that reducing points for ambulation may place less emphasis on this critical task, potentially leading to higher fall rates and, consequently, increased hospitalizations. The commenter also noted that while bathing points were significantly increased, which they

stated was beneficial, the commenter stated the increase should not be as substantial, especially given the larger reduction in points for toilet transfers and ambulation. Additionally, some commenters expressed concern that the proposed changes to the case-mix weights contribute to substantial year-to-year payment variances, which may have a significant financial impact on many providers as case-mix weights are driven lower. These commenters noted that this variability in payment could create financial challenges for providers, particularly those already dealing with increasing costs and labor shortages.

Response: While we recognize that commenters have consistently raised concerns regarding the annual recalibration of case mix weights since the policy's initial finalization, we continue to believe that annual recalibration of PDGM case mix weights is essential. This approach promotes accurate weighting of the case mix weights to reflect current home health resource utilization, changes in utilization patterns, and the characteristics of patients currently receiving home health services. Prolonging recalibration beyond an annual schedule could result in greater variation in case mix weights, compared to recalibrating using the most recent utilization data. Therefore, we believe that utilizing calendar year 2023 data to recalibrate the calendar year 2025 case-mix weights is appropriate. We direct commenters to review the calendar year 2019 HH PPS final rule with comment (83 FR 56502) for the finalized case-mix adjustment methodology, as well as the detailed steps taken to determine the case-mix weight for each of the 432 different PDGM payment groups, which are outlined in this final rule. Furthermore, it is important to note that both the recalibration of the PDGM case-mix weights and updates to the HH PPS are implemented in a budget-neutral manner as statutorily required in section 1895(b)(3)(A)(i) of the Act, ensuring that changes to case-mix weights, functional impairment levels, comorbidity adjustments, and updated wage data do not impact overall payments in the aggregate.

We appreciate the commenters' recognition of our efforts to recalibrate case-mix weights using the most current data available. Regarding concerns about the downgrading of points for

toilet transfers and ambulation, we recognize the importance of accurately reflecting the resource needs associated with these tasks. However, the reallocation of points is driven by the need to maintain budget neutrality, and any adjustments are made based on current utilization data and resource allocation. While a few commenters expressed support for the idea of non-budget neutral recalibration, it is important to note that, as statutorily required by section 1895(b)(3)(A)(i) of the Act, any adjustments to case-mix weights must be made in a budget neutral manner to ensure that the aggregate level of payments resulting from changes in case-mix weights remains consistent.

We also acknowledge the concern that case-mix weight changes may lead to year-to-year payment variances and potential financial challenges for providers. The intent of recalibration is to align payments with actual resource use while maintaining overall budget neutrality. As always, we will continue to evaluate the impact of these adjustments and consider the evolving needs of the home health population.

Final Decision: We are finalizing the recalibrated case-mix weights for CY 2025, updated with claims data as of July 11, 2024. We did not receive any comments on the proposed case-mix weight budget neutrality factor. Therefore, we are finalizing the proposal to implement the changes to the PDGM case-mix weights in a budget neutral manner by applying a case-mix budget neutrality factor to the CY 2025 national, standardized 30-day period payment rate. As stated previously, the final case-mix budget neutrality factor for CY 2025 will be 1.0039.

5. 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 webpage.

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 will 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 will 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 (UTI). 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 did not propose a reassignment of N30.00- (acute cystitis) at this time.

Comment: We received a comment requesting we reassign N30.00- (acute cystitis) to receive the same clinical grouping and comorbidity subgroup as an unspecified UTI. Another commenter stated they believe diagnoses were missing from comorbidity groups, such as sepsis that was not grouped with UTI. Other commenters requested rheumatic mitral value diseases I05.– and aortic rheumatic valve diseases I06.– should be assigned to the comorbidity subgroup Heart 9 and that F01., Vascular dementia, be reassigned to the behavioral health clinical group.

Response: We appreciate the commenters diligent review of the ICD–10–CM diagnosis codes and their assigned clinical and comorbidity group. We remind readers that not all diagnosis codes are assigned a clinical group and/or a comorbidity group under the HH PPS payment policy. As we did not propose any reassignments at this time, these comments are considered out of scope for this rule. Additionally, to evaluate clinically and, when needed, statistically, a request for a diagnosis code's clinical group or comorbidity subgroup reassignment, we require the current assignment of the diagnosis code(s), the requested reassignment, and any supporting evidence for the reassignment (for example, similar clinical management and services). As we stated in the CY 2023 HH PPS final rule (87 FR 66808) if an ICD–10–CM diagnosis code is to be reassigned from one clinical group and/ or a comorbidity subgroup to another clinical/comorbidity group, either through a request from the public or

internal analysis, as the change may affect payment, it is necessary to propose these changes through notice and comment rulemaking. Lastly, while we attempt to evaluate requests in the order in which they are received, the length of time needed to sufficiently evaluate a request varies. For future requests for ICD-10 code reassignments, readers can send their request(s) to the Home Health Policy mailbox: HomeHealthPolicy@cms.hhs.gov.

E. CY 2025 Home Health Payment Rate Updates

1. Final 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 will be 74.9 percent, and the non-labor-related share will be 25.1 percent. A detailed description of how we rebased the home health 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 IHS Global Inc.'s (IGI) 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 was 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 was 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 was estimated to be 0.5 percentage point for CY 2025. Therefore, the proposed productivity-adjusted CY 2025 home health market basket update was 2.5 percent (3.0 percent market basket percentage increase, reduced by a 0.5 percentage point productivity adjustment). Furthermore, we proposed that if more recent data subsequently became 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.

For this final rule, based on updated data from IGI's third quarter 2024 forecast with historical data through the second quarter of 2024, the 2021-based home health market basket

percentage increase for CY 2025 is 3.2 percent reduced by a 0.5 percentage point productivity adjustment which results in a final CY 2025 update percentage of 2.7 percent.

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 was 0.5 percent (2.5 percent minus 2 percentage points). For this final rule, for HHAs that do not submit the required data for CY 2025, the final home health payment update percentage is 0.7 percent (2.7 percent minus 2 percentage points).

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

Comment: A few commenters stated that they appreciate the market basket update and that they support the methodology resulting in a proposed positive payment update of 2.5 percent.

Response: We thank the commenters for their support.

Comment: Some commenters asserted that the proposed update is not enough to account for the increase in costs that home health agencies have faced. Commenters stated that home health agencies continue to face stubborn and rising inflation which they state affects the costs of medical supplies, medications, materials, utilities, transportation, as well increases in labor costs. They note that retention and recruitment of staff remains a priority, but there have been challenges due to personnel shortages and the need to compete with other health care sectors, which continues to apply upward pressure to the cost of labor. Specifically, a commenter stated that their labor costs have increased nearly 12 percent between 2021 and 2024, and that they are projecting significant future cost increases to recruit and retain the workforce necessary to meet rapidly increasing demand.

A commenter suggested CMS examine trends relative to IHS Global Inc.'s forecasts to determine whether more recently available data than used for the final CY 2025 rule would result in a higher market basket update and determine whether additional updates could be made during the course of CY 2025 to provide additional support to home health and other providers.

Some commenters stated that since 2021, they believe IGI's forecasted growth for the home health market basket has shown a consistent trend of under-forecasting actual market basket growth. They stated they were cognizant of the fact that forecasts will always be imperfect, but the commenters claimed that in the past, they have been more balanced. However, with what they state are four straight years of under-forecasts, the commenters were concerned that there is a more systemic issue with IGI's forecasting. They stated that missed forecasts have a significant and permanent impact on providers. The commenters claimed that this has resulted in ongoing and permanent underpayments to HHAs that is totaling approximately $700 million annually.

The commenters stated that in addition to inaccurate forecasts, the underlying market basket itself may have shortcomings that fail to properly capture growth. They noted that there has been a very large growth in providers' costs in the last several years, and that it is confounding how providers with labor-intensive services could have a change in the actual market basket growth that is 4 percentage points below general inflation as measured by the CPI-U. Commenters urged CMS to re-examine the market basket and forecast methodology, and a commenter urged CMS to provide greater transparency regarding the forecast methodology so that it might benefit from stakeholder input.

Response: We appreciate the commenters' concerns. We are required to update HH PPS payments by the market basket update adjusted for productivity, as directed by section 1895(b)(3)(B) of the Act. Specifically, section 1895(b)(3)(B)(iii) of the Act states that the increase factor shall be based on an appropriate percentage increase in a market basket of goods

and services included in home health services in the same manner as the market basket percentage increase under section 1886(b)(3)(B)(iii) of the Act is determined and applied to the mix of goods and services comprising inpatient hospital services for the fiscal year or year. There is not currently a mechanism in place to allow for additional updates during the course of CY 2025, as was suggested by the commenter, beyond the percentage increase described here.

The home health market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the home health market basket update would reflect the prospective price pressures described by the commenters (such as wage growth or higher energy prices) but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used. We note that cost changes (that is, the product of price and quantities) would only be reflected when the base year weights are updated to a more recent time period.

We would also highlight that the market basket percentage increase is a forecast of the price pressures that HHAs are expected to face in 2025. IHS Global Inc. (an Affiliate of S&P Global Inc.) is a nationally recognized economic and financial forecasting firm (a participant in the Blue Chip Economic Indicators®) with which CMS contracts to forecast the components of the market baskets. While this most recent period has been marked by a consistent under forecasting of the market basket forecast, over longer periods the forecasts have generally averaged close to the historical measures. We note that when developing its forecasts of employment cost indices, IHS Global Inc. considers overall labor market conditions (including a rise in contract labor employment due to tight labor market conditions) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the HHA. CMS will continue to monitor the methods associated with the market basket forecasts to ensure there are not underlying systematic issues in the forecasting approach.

While we did not propose to rebase or revise the home health market basket in the CY 2025 HH PPS proposed rule, we note that we finalized the 2021-based home health market basket in the CY 2024 HH PPS final rule (88 FR 77726). At the time of the CY 2024 rulemaking cycle, the 2021 Medicare cost report data was the most comprehensive data source available. While we typically rebase in regular intervals (roughly every four years), we monitor the Medicare cost report data to assess whether rebasing on a more frequent schedule is technically appropriate, and we will continue to do so in the future. In addition, we welcome any suggestions for technical improvements to the home health market basket and note that any changes would be proposed and established through notice and comment rulemaking.

At the time of the CY 2025 HH PPS proposed rule, based on the IHS Global Inc. first quarter 2024 forecast with historical data through the fourth quarter of 2023, the 2021-based home health market basket update was forecasted to be 3.0 percent for CY 2025, reflecting forecasted compensation price growth of 3.4 percent. This reflects an expectation that the growth in compensation costs will ease relative to the 2021-2023 period but remain elevated relative to historical compensation growth rates (which averaged 2.1 percent in the 10-year period from 2011 through 2020). We appreciate the commenter's concern regarding inflationary pressure and the request to use more recent data to determine the CY 2025 home health market basket update. In the CY 2025 HH PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2025 home health market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2025. Based on IHS Global Inc.'s third quarter 2024 forecast with historical data through the second quarter of 2024, we are projecting a CY 2025 home health market basket update of 3.2 percent (reflecting forecasted compensation price growth of 3.5 percent) and a productivity adjustment of 0.5 percentage point. Therefore, for CY 2025 a final productivity-adjusted home health market

basket update of 2.7 percent (3.2 percent reduced by 0.5 percentage point) will be applicable, compared to the 2.5 percent productivity-adjusted home health market basket update that was proposed.

Comment: Several commenters stated that CMS should recognize the financial impact of its forecasting error with respect to the annual Market Basket Index updates from 2021 and 2022 and exercise its authority to implement a one-time adjustment of 5.2 percent to account for the forecasting error. A few commenters suggested alternative forecast error adjustments ranging from approximately 4.4 to 5.7 percent to account for under forecasts in the period from 2021 through 2023.

Response: The home health market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the CY 2025 market basket update in this final rule reflects historical data through the second quarter of CY 2024 and forecasted data from the third quarter of CY 2024 through the fourth quarter of CY 2025. There is currently no mechanism to adjust for market basket forecast error in the home health payment update. A forecast error for a market basket update is equal to the actual market basket percentage increase for a given year less the forecasted market basket percentage increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative, as has occurred since the implementation of the HH PPS.

Over most of this history the forecast errors were smaller in magnitude, with the largest error prior to 2021 being an over forecast of 1.2 percentage points in 2009. More recently the home health market basket has been under forecast, as noted by the commenters, with larger errors occurring for 2021 through 2023. The cumulative forecast error since HH PPS inception (fiscal year 2002 to CY 2023, excluding CY 2018 and CY 2020 when the market basket update was statutorily mandated) is -0.7 percent. The recent forecast errors were largely a function of

uncertainty in the overall economy and the health sector specifically due to the nature of the public health emergency and the unforeseen rapidly accelerating inflationary environment.

For this final rule, we have incorporated more recent historical data and forecasts to capture the price and wage pressures facing HHAs and believe it is the best available projection of inflation to determine the applicable percentage increase for the HHA payments in CY 2025.

Comment: A commenter stated they are disappointed that CMS has not taken increased workforce safety costs into consideration. They indicated that workforce safety is an area of growing concern for the home health industry at large and it will take significant investments in training, security and equipment to keep home health clinicians safe while working in the home and community. The commenter stated that there is currently no area to report many of these unique environmental and safety costs on the Medicare cost report. The commenter stated that they believe that CMS needs to work with the home health industry to ensure that workplace safety costs and other unique expenditures related to home health are considered when determining the home health payment rate update.

Response: We recognize the importance of ensuring workforce safety. CMS reminds commenters that these costs may be recorded under the Plant Operation & Maintenance cost center, which includes costs associated with "protecting employees, visitors, and HHA property."

As detailed in the CY 2024 HH PPS final rule (88 FR 77728), costs recorded in the overhead cost centers are used to derive the major cost weights, and thus any significant changes in the volume or intensity of investment since the base year (currently 2021) would be a factor in the cost weights when the home health market basket is next rebased.

Final Decision: After consideration of public comments, we are finalizing the home health payment update percentage for CY 2025 based on the most recent forecast of the home health market basket percentage increase and productivity adjustment at the time of rulemaking. Based on IHS Global Inc.'s third quarter 2024 forecast with historical data through the second

quarter of 2024, we are projecting a CY 2025 home health market basket update of 3.2 percent and a productivity adjustment of 0.5 percentage point. Therefore, we are finalizing for CY 2025 a final productivity-adjusted home health market basket update of 2.7 percent (3.2 percent reduced by 0.5 percentage point).

2. Adoption of the CBSA Delineations for the HH PPS 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 0.8519. 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 will propose any updates from OMB Bulletin No. 20-01 in future rulemaking. After reviewing OMB Bulletin No. 20-01, we determined that the changes in Bulletin 20-01 encompassed delineation changes that did 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. In the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we finalized a policy that the CY HH PPS wage index will include a permanent 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 will 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 will 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 final rule, because we proposed to adopt the revised OMB delineations, we also proposed 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 will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels. We proposed 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. The proposal was 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 fiscal year (FY) 2005 IPPS final rule (69 FR 49029 through 49032), we determined the best course of action will 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. In the CY 2025 HH PPS proposed rule, we stated that 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) (89 FR 55364). 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 also proposed to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

Final Decision: We did not receive any comments on our proposal to continue to treat Micropolitan Areas as rural and to include those areas in the calculation of each State's rural wage index. We are finalizing this policy as proposed.

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

In a June 6, 2022, **Federal Register** notice (87 FR 34235 through 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 evaluated the change and proposed 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 provided the crosswalk in table 26 of the proposed rule (89 FR 55364) for counties located in Connecticut with the current and proposed Federal Information Processing Series (FIPS) county and county-equivalent codes and CBSA assignments.

TABLE 13: CROSSWALK OF CONNECTICUT COUNTY EQUIVALENTS

FIPS County Code	County	Old CBSA or Non-urban Area	New FIPS County Code	CY 2025 Planning Region	Redesignated 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	50003

Note: Beginning in CY 2025, the Northeastern Planning Region will be redesignated into rural Connecticut but must use transition code 50003 for home health claims processing to receive the correct wage index value.

Final Decision: We did not receive any comments on our proposal to adopt the Connecticut planning regions as county equivalents for wage index purposes. We are finalizing this policy as proposed. The crosswalk in table 13 includes counties located in Connecticut with the current and final FIPS county and county-equivalent codes and CBSA/transition code assignments.

c. Urban Counties That Will Become Rural

In the CY 2025 HH PPS proposed rule, we inadvertently omitted Windham County, CT from the list of counties that would become rural under the revised OMB statistical area delineations (based upon OMB Bulletin No. 23-01). For this final rule, Windham County has been included. Therefore, there are a total of 54 counties (and county equivalents) that are currently considered urban that will be considered rural beginning in CY 2025. Table 14 lists the 54 counties that will become rural if we finalize our proposal to implement the revised OMB delineations.

TABLE 14: URBAN COUNTIES THAT WILL 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

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name
09015	WINDHAM	CT	49340	Worcester, MA-CT
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
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

We invited public comment on our proposal to redesignate the urban counties in table 14 as rural based on the revised OMB delineations from OMB Bulletin No. 23-01.

Comment: Several commenters expressed concern with the proposal to redesignate urban counties as rural based on the revised delineations from OMB Bulletin No. 23-01. A few commenters stated that changes to the wage index that would move some agencies from an urban designation to a rural one would further reduce agency reimbursement at a time when rural agencies are facing increased challenges recruiting and retaining employees. Another commenter stated that utilizing the revised OMB data for the CBSAs results in even more disparity between urban and rural agencies than there was under the prior delineations. This commenter stated that the one-year wage index cap of 5 percent is insufficient to mitigate rate decreases and that many newly classified rural agencies will be severely impacted.

Response: We appreciate the concerns raised by the commenters. However, we continue to 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 note that unlike other payment systems, the appropriate home health 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) and not the agency's location. While some urban counties are becoming rural based on the revised delineations, HHAs are able to serve beneficiaries in more than one county including counties that remain designated as urban. Furthermore, as discussed later in this final rule, we believe that applying the permanent 5-percent cap policy at the county level would mitigate potential negative impacts experienced by HHAs who provide services in counties that have been redesignated as rural. We proposed to apply the permanent 5-percent cap at the county level so that counties that 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 will have a CY 2025 wage index that is not 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. We also proposed that the 5-percent cap would continue to be applied in these counties until a county's current

calendar year wage index under the revised delineations is not less than 95 percent of the wage index from the previous calendar year. Therefore, we believe the 5-percent cap applied at the county level is sufficient to mitigate any negative impacts of adopting the revised delineations.

Final Decision: After consideration of public comments, we are finalizing the proposal to redesignate the 54 urban counties listed in table 14 as rural for purposes of the HH PPS wage index beginning in CY 2025.

d. Rural Counties That Will 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 will be considered located in urban areas under the revised OMB delineations beginning in CY 2025. Table 15 lists the 54 counties that will be urban if we finalize our proposal to implement the revised OMB delineations.

TABLE 15: RURAL COUNTIES THAT WILL CHANGE TO URBAN STATUS

FIPS County Code	County Name	State	Final CY 2025 CBSA	Final 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

FIPS County Code	County Name	State	Final CY 2025 CBSA	Final CY 2025 CBSA Name
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

Final Decision: We did not receive public comments on our proposal to redesignate the 54 rural counties listed in table 15 as urban based on the revised OMB delineations from OMB Bulletin No. 23-01. Therefore, we are finalizing the policy as proposed.

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

In addition to some rural counties becoming urban and some urban counties becoming rural, several urban counties will 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 will involve a change only in CBSA name or number, while the CBSA will continue to encompass the same constituent counties. For example, CBSA 35154 (New Brunswick-Lakewood, NJ) will 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 will remain the same. In other cases, only the name of the CBSA will be modified. Table 16 lists CBSAs that will change in name and/or CBSA number only, but the constituent counties will not change (except in instances where an urban county became rural or a rural county became urban, as discussed in the previous section).

TABLE 16: URBAN AREAS WITH CBSA NAME AND/OR NUMBER CHANGE

Current CBSA Code	Current CBSA Name	Final CY 2025 CBSA Code	Final 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
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 will be moved and subsumed by another CBSA in CY 2025. Table 17 lists the CBSAs that, under our proposal to adopt the revised OMB statistical area delineations, will be subsumed by another CBSA.

TABLE 17: URBAN AREAS THAT WILL BE SUBSUMED BY ANOTHER CBSA

Current CBSA Code	Current CBSA Name	Final CY 2025 CBSA Code	Final 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 will shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. In another type of change, some CBSAs have counties that will 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 will move from CBSA 47894 (Washington-Arlington-Alexandria, DC-VA-MD-WV) into CBSA 47764 (Washington, DC-Md). Calvert County, MD will 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) will move into CBSA 11694 (Arlington-Alexandria-Reston, VA-WV). Finally, in some cases, a CBSA will lose counties to another existing CBSA if we adopt the new OMB delineations. For example, Grainger County, TN will move from CBSA 34100 (Morristown, TN) into CBSA 28940 (Knoxville, TN). Table 18 lists the 73 urban counties that will move from one urban CBSA to a new or modified urban CBSA if we adopt the revised OMB delineations.

TABLE 18: COUNTIES THAT WILL CHANGE TO A DIFFERENT URBAN CBSA

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name	Final CY 2025 CBSA	Final 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
12101	PASCO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
39123	OTTAWA	OH	45780	Toledo, OH	41780	Sandusky, OH

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name	Final CY 2025 CBSA	Final CY 2025 CBSA Name
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

A summary of the general comments on our proposals to adopt the revised delineations from OMB Bulletin No. 23-01 appears below:

Comment: Some commenters, including MedPAC, were generally supportive of the proposals to adopt the revised delineations from OMB Bulletin No. 23-01. A commenter expressed support for the proposal to adopt the new OMB delineations as described in OMB Bulletin 23-01 for the HH PPS wage index effective beginning in CY 2025. This commenter agreed 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 variations in wage levels. Another commenter stated that until a new home health wage index can be implemented, the commenter supports CMS' proposal to continue using OMB's most recent statistical area delineations for the hospital wage index.

Response: We thank the commenters for their support.

Comment: A commenter opposed what they describe as the automatic adoption of the revised OMB delineations. This commenter stated that adopting the new delineations by default is in opposition to both OMB guidance and the Metropolitan Areas Protection and Standardization Act of 2021 (MAPs Act). This commenter stated that CMS has not provided any rationale or explanation for why relying on the updated CBSAs is appropriate and that rather than simply adopting the OMB CBSAs by default, CMS must make a fact-specific determination of those CBSAs' suitability for Medicare payment purposes, including whether it would be appropriate to use additional data to modify OMB's delineation to ensure that such changes are appropriate for purposes of defining regional labor markets for home health workers.

Response: We acknowledge the commenter's concerns about adopting CBSA changes. We do not agree with the commenter's assertion that this is "by default" or that CMS has not provided rationale for the proposed adoption of the revised CBSA delineations for CY 2025. The MAPS Act specifically states that ''this act limits the automatic application of, and directs the

Office of Management and Budget (OMB) to provide information about, changes to the standards for designating a core-based statistical area (CBSA) . . .'' We believe our proposed rule meets the requirements of the MAPS Act, because we have not automatically applied the revised CBSAs outlined in OMB Bulletin 23–01. Rather, through notice and comment rulemaking, we proposed the adoption of the revised CBSA delineations. Further, we stated our rationale for adopting the revised CBSA delineations, in that we believe it is important for the HH PPS to use, as soon as is reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to date payment system that reflects the reality of population shifts and labor market conditions. We also stated that we believe that using the most current delineations would increase the integrity of the HH PPS wage index system by creating a more accurate representation of geographic variations in wage levels. With respect to the suggestion that CMS consider whether it would be appropriate to use additional data to ensure that such changes are appropriate for purposes of defining regional labor markets for home health workers, we do not believe use of such additional analysis is necessary. Using the latest available labor market area delineations based on the latest available CBSA delineations established by OMB inherently reflects current population and labor market conditions and as such, results in a more accurate payment system.

Comment: A few commenters expressed concern with specific redesignations in their areas. A commenter stated that the proposed adoption of the latest OMB delineations for the home health wage index will significantly impact several Florida regions and that high-cost areas such as Miami-Fort Lauderdale-West Palm Beach, Tampa-St. Petersburg-Clearwater, and Orlando-Kissimmee-Sanford are likely to experience notable reductions in their wage index values. This commenter recommended that CMS reconsider the proposed adoption of the new delineations by accounting for the distinctive economic and demographic factors influencing high-cost regions in Florida.

Several commenters opposed the delineation change for rural Puerto Rico where there is now a hospital in rural Puerto Rico from which hospital wage data can be derived. These commenters stated the payment calculations to providers will ultimately be reduced by 20.64 percent when using a wage index of 0.2520 vs 0.4047. The commenters stated that providers are unable to operate at a 20 percent reduction, particularly in the face of increasing costs and expressed concern that this reduction will lead to adverse impacts for beneficiaries as the labor market further shrinks and healthcare workers exit the Puerto Rico market for other areas or industries.

A commenter opposed the impact of the adoption of the revised delineations in Nassau, Suffolk, and Westchester Counties in New York state. This commenter requested CMS consider the impact of the wage index changes on Core-Based Statistical Areas (CBSAs) with increasing labor costs and the impact of these reductions on hospice, home health, and other home-and community-based providers in relation to institutional care providers

Another commenter expressed concern about the impact of county reclassifications on home health agencies serving Dukes and Nantucket Counties in Massachusetts. The commenter stated that as a result of the reclassification of Franklin County, the wage index for Dukes and Nantucket counties has dropped by 10 percent in the last 2 years and would drop an additional 10 percent over the next 2 years and that Medicare beneficiaries on those island communities are already experiencing limited access to home health services. The commenter stated that the proposed 5 percent cut will exacerbate that access problem and recommended CMS reverse the proposed 5 percent cut to the wage index for Dukes and Nantucket Counties to preserve access to home health services in those counties.

Response: We appreciate the concerns expressed by commenters regarding specific impacts of implementing the revised designations. While we understand these concerns, we believe that implementing the revised OMB delineations will create more accurate representations of labor market areas nationally and result in home health wage index values

being more representative of the actual costs of labor in a given area. Although these comments only addressed the negative impact on certain areas, it is important to note that there are many geographic locations and home health providers that will experience positive impacts upon implementation of the revised CBSA designations. We acknowledge there are areas that will experience a decrease in their wage index but believe that the permanent 5-percent cap policy provides an adequate safeguard against any significant payment reductions in CY 2025 while improving the accuracy of the payment adjustment for differences in area wage levels. Therefore, we believe that it is appropriate to implement the new OMB delineations without further delay.

Final Decision: We are finalizing our proposals to adopt the revised OMB delineations from OMB Bulletin No. 23-01.

f. 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 will 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 will 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 will not be less than 95 percent of its wage index calculated in the prior CY.

In the CY 2025 HH PPS proposed rule, we stated 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 proposed 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 will not experience more than a five percent decrease in wage index from the previous calendar year. Specifically, we proposed for CY 2025, that the 5-percent cap will 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 proposed 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 after the redesignation. Specifically, some counties that change OMB designations will 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 will receive the cap will 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 proposed 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 will 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[11] wage index transition codes will 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 proposed that Lamar County will be redesignated into the Rural Georgia Code 99911. Because the wage index value of rural Georgia is more than a 5-percent

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

decrease from the wage index value that Lamar County previously received under CBSA 12060, the CY 2025 wage index for Lamar County will 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, a transition code will be used on a home health claim instead of rural Georgia code 99911.

We also proposed 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 will 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 will use the assigned transition code 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 final counties that will require a transition code and the corresponding 50XXX codes are shown in table 19 and will also be shown in the CY 2025 HH PPS wage index file. Table 19 includes a list of counties that have changed designation and must use a transition code beginning in CY 2025. This list is comprised of counties that are redesignated into a new CBSA or rural area and will receive the 5-percent cap on wage index decreases. These counties must use a transition code because the wage index for that county is higher than all other constituent counties that make up the CBSA or rural area (like the earlier example for Lamar County, GA). Additionally, the list also includes counties that move into a new CBSA or rural area and have a different wage index value because the constituent counties that make up the CBSA or rural receive the 5-percent cap for CY 2025 while the county that moves into the CBSA or rural area

does not. For example, rural area 99922 rural Massachusetts is comprised of FIPS code 25007 Dukes County, FIPS code 25019 Nantucket County and the redesignated FIPS code 25011 Franklin County. Dukes County and Nantucket County were part of rural area 99922 Massachusetts for CY 2024 and will receive the 5-percent cap because the CY 2025 wage index for rural area 99922 is more than a 5-percent decrease from the CY 2024 wage index for rural area 99922. However, Franklin County was included in CBSA 44140 Springfield, MA, in FY 2024 and the uncapped CY 2025 wage index for rural area 99922 is higher than the CY 2024 wage index for CBSA 44140. In this example, Franklin County, MA, would receive the uncapped wage index for rural Area 99922 while Dukes and Nantucket counties receive the 5-percent capped wage index. Therefore, HHAs that serve beneficiaries in Franklin County, MA, must use the transition code 50012 on home health claims instead of rural area 99922 Rural Massachusetts.

TABLE 19: COUNTIES THAT WILL USE A WAGE INDEX TRANSITION CODE

FIPS County Code	County Name	CY 2024 CBSA	CY 2024 CBSA Name	Redesignated CBSA or Rural Area	Redesignated CY 2025 CBSA Name	CY 2025 Transition Code
01129	WASHINGTON	33660	Mobile, AL	99901	ALABAMA	50001
05047	FRANKLIN	22900	Fort Smith, AR-OK	99904	ARKANSAS	50002
09150	NORTHEASTERN CONNECTICUT	49340	Worcester, MA-CT	99907	CONNECTICUT	50003
13171	LAMAR	12060	Atlanta-Sandy Springs-Alpharetta, GA	99911	GEORGIA	50004
15005	KALAWAO	99912	HAWAII	27980	Kahului-Wailuku, HI	50005
16077	POWER	38540	Pocatello, ID	99913	IDAHO	50006
17183	VERMILION	19180	Danville, IL	99914	ILLINOIS	50007
18133	PUTNAM	26900	Indianapolis-Carmel-Anderson, IN	99915	INDIANA	50008
21101	HENDERSON	21780	Evansville, IN-KY	99918	KENTUCKY	50009
22045	IBERIA	29180	Lafayette, LA	99919	LOUISIANA	50010
24009	CALVERT	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD	50011
24047	WORCESTER	41540	Salisbury, MD-DE	99921	MARYLAND	50012
25011	FRANKLIN	44140	Springfield, MA	99922	MASSACHUSETTS	50013
26155	SHIAWASSEE	29620	Lansing-East Lansing, MI	99923	MICHIGAN	50014
27075	LAKE	20260	Duluth, MN-WI	99924	MINNESOTA	50015
27133	ROCK	99924	MINNESOTA	43620	Sioux Falls, SD-MN	50016
32019	LYON	99929	NEVADA	39900	Reno, NV	50017
34009	CAPE MAY	36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ	50018
36123	YATES	40380	Rochester, NY	99933	NEW YORK	50019
37077	GRANVILLE	20500	Durham-Chapel Hill, NC	99934	NORTH CAROLINA	50020
37087	HAYWOOD	11700	Asheville, NC	99934	NORTH CAROLINA	50021
39123	OTTAWA	45780	Toledo, OH	41780	Sandusky, OH	50022
42103	PIKE	35084	Newark, NJ-PA	99939	PENNSYLVANIA	50023
51113	MADISON	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	99949	VIRGINIA	50024
51175	SOUTHAMPTON	47260	Virginia Beach-Norfolk-Newport News, VA-NC	99949	VIRGINIA	50025
51620	FRANKLIN CITY	47260	Virginia Beach-Norfolk-Newport News, VA-NC	99949	VIRGINIA	50025
54035	JACKSON	16620	Charleston, WV	99951	WEST VIRGINIA	50026
54043	LINCOLN	16620	Charleston, WV	99951	WEST VIRGINIA	50026
54057	MINERAL	19060	Cumberland, MD-WV	99951	WEST VIRGINIA	50027
72001	ADJUNTAS	38660	Ponce, PR	99940	PUERTO RICO	50028
72023	CABO ROJO	41900	San Germ n, PR	32420	Mayagüez, PR	50029
72079	LAJAS	41900	San Germán, PR	32420	Mayagüez, PR	50029
72121	SABANA GRANDE	41900	San Germán, PR	32420	Mayagüez, PR	50029
72125	SAN GERMAN	41900	San Germán, PR	32420	Mayagüez, PR	50029
72055	GUANICA	49500	Yauco, PR	99940	PUERTO RICO	50030
72059	GUAYANILLA	49500	Yauco, PR	38660	Ponce, PR	50031
72111	PENUELAS	49500	Yauco, PR	38660	Ponce, PR	50031
72153	YAUCO	49500	Yauco, PR	38660	Ponce, PR	50031
72081	LARES	10380	Aguadilla-Isabela, PR	99940	PUERTO RICO	50032

FIPS County Code	County Name	CY 2024 CBSA	CY 2024 CBSA Name	Redesignated CBSA or Rural Area	Redesignated CY 2025 CBSA Name	CY 2025 Transition Code
72141	UTUADO	10380	Aguadilla-Isabela, PR	99940	PUERTO RICO	50032
72083	LAS MARIAS	32420	Mayagüez, PR	99940	PUERTO RICO	50033

The following is a summary of the comments on the proposal to use the permanent 5-percent cap applied at the county level as a transition.

Comment: A few commenters were supportive of the use of the permanent 5-percent cap to mitigate any adverse effects of adopting the revised OMB delineations. MedPAC stated that the Commission supports having a policy to cap and phase in the wage index reductions that a provider can experience in a given year. Another commenter thanked CMS for implementing the 5-percent cap on wage index decreases as a policy to combat ongoing wage index inequities.

Response: We appreciate the commenters support.

Comment: A few commenters recommended other changes to the finalized 5-percent cap policy. MedPAC recommended that the cap should be applied to both increases and decreases in a given year. Several commenters recommended that the cap be lowered to two percent, while a commenter suggested the cap should be no more than three percent. A commenter requested that CMS institute a one-time zero wage index adjustment in all CBSAs where there is a negative adjustment, while another commenter recommended that the 5-percent cap should be implemented in a non-budget neutral manner.

A commenter stated that the 5-percent cap is helpful as a general measure to stabilize wage index values from year to year, but that does not negate the need to implement a transition period specific to wage index changes resulting from revised CBSA delineations. This commenter recommended a three-year transition period to allow for a wage index transition consistent with prior updates to the CBSA categorization due to OMB updates.

Response: We appreciate commenters recommendations for changes to the finalized cap policy. However, in the CY 2025 HH PPS proposed rule, we did not propose to make changes to the finalized 5-percent cap policy outside of the proposal to apply the 5-percent cap at the county level. Therefore, these comments are outside the scope of the proposed rule. Any changes to the finalized cap policy beyond the proposal to apply the cap at the county level would need to go through notice and comment rulemaking. We continue to believe that a 5-percent cap would

most effectively mitigate any significant decreases in a geographic area's wage index for a calendar year, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, we believe that the 5-percent cap on wage index decreases provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face year to year. Therefore, we do not believe that any transition is appropriate at this time.

Comment: A commenter expressed support for the proposal to apply the 5-percent cap at the county level. This commenter stated that they strongly believe that the wage index for any county or service area should not decrease by more than five percent in any given year and expressed support for the proposal that each Transitional CBSA, in which the included county(s) would have any reduction to their wage index limited to five percent from the previous year, should remain active until such time that the county(s) included would be able to be included in their new CBSA/Service Area when the reduction to their Wage Index would be five percent or less.

This commenter also recommended that CMS provide a crosswalk in CSV or Excel format of any/all changes any year in which there are changes such as these, stating that the crosswalk should include the Social Security Administration (SSA) Code, FIPS Code, CBSA Code (and transition code where applicable), and the Wage Index (and transition wage index where applicable) for every unique County or Service Area covered under the Medicare program. Another commenter requested that CMS carefully plan communication to impacted facilities so that they are clear regarding what number to use on home health claims.

Response: We thank the commenters for their support. We acknowledge the importance of providing an accurate crosswalk for the CY 2025 wage index that highlights the changes due to the revised OMB delineations, specifically in counties that will require a transition code. Therefore, we are listing the counties that will require a transition code in CY 2025 in table 19 and we are also including this table in the CY 2025 wage index file. The CY 2025 wage index

file provides a crosswalk between the current OMB delineations and the final revised OMB delineations that will be in effect in CY 2025. This file shows each state and county and its corresponding final wage index along with the previous CBSA number, the final CBSA number or alternate identification number, and the final CBSA name. The list of counties that will require a transition code beginning in CY 2025 will also be included in the CY 2025 Home Health Rate Update Change Request that can be located at https://www.cms.gov/medicare/regulations-guidance/transmittals.

Final Decision: We are finalizing our proposal to adopt the revised OMB delineations from OMB Bulletin 23–01, and will also apply the permanent 5-percent cap on wage index decreases at the county level with the use of a transition code, so that counties impacted by the revised designations will receive a 5-percent cap on any decrease in a geographic area's wage index value from the wage index value from the prior calendar year for CY 2025. We are also finalizing our proposal that, beginning in CY 2025, counties that have a different wage index value than the CBSA or rural area into which they are designated due to the application of the 5-percent cap (including redesignated counties that will receive the 5-percent cap and redesignated counties that move into a CBSA or rural area where all other constituent counties receive the 5-percent cap) will use a wage index transition code. These special codes are five digits in length and begin with ''50.'' The 50XXX wage index transition codes will 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. Finally, we are finalizing the policy that the 5-percent cap will 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. In order to capture the correct wage index value, the county will continue to use the assigned 50XXX transition code until the county's wage index value

calculated for that fiscal year using the new OMB delineations is not less than 95 percent of the county's capped wage index from the previous calendar year.

The final 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 revised OMB delineations that will be in effect in CY 2025. This file shows each state and county and its corresponding final wage index along with the previous CBSA number, the final CBSA number or transition code, and the finalized CBSA name. The final 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. Final 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 proposed 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 proposed 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 final CY 2025 HH PPS wage index will 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 will 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 proposed 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 proposed the CY 2025 wage index value for Hinesville, GA, would be 0.8608. With updated data, the final wage index value for Hinesville, GA, will be 0.8824.

For rural areas that do not have inpatient hospitals, we proposed 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 the CY 2025 HH PPS proposed rule, we proposed 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 proposed 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 resulted in a proposed CY 2025 HH PPS wage index of 0.8334 for rural North Dakota. For this final rule using updated data, the final wage index value for rural North Dakota

will be 0.8503 which is the average pre-floor, pre-reclassified wage index values after the application of the 5-percent cap of the four contiguous counties outlined in table 20.

TABLE 20: CY 2025 WAGE INDEX FOR RURAL NORTH DAKOTA

CBSA Code	CBSA Name	CY 2025 HH PPS Wage Index
13900	Bismarck, ND	0.8982
22020	Fargo, ND-MN	0.8726
24220	Grand Forks, ND-MN	0.7832
33500	Minot, ND	0.8470*
	Final CY 2025 HH PPS Wage Index	**0.8503**

Note: CBSA 33500 Minot, ND is adjusted by the 5-percent cap.

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 will 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 proposed 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 was 0.2520. However, because 0.2520 is more than a 5 percent decline in the CY 2024 wage index, the 5-percent cap will be applied. We proposed 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 resulted in a proposed wage index value of 0.3845. For this final rule, using updated data, the final unadjusted wage index value for rural Puerto Rico is 0.2510. However, because 0.2510 is more than a 5 percent decline in the CY 2024 wage index, the 5-percent cap will be applied. The final CY 2025 5-percent cap adjusted wage index for rural Puerto Rico will be set equal to 95 percent of the CY 2024 wage index, which results in a final 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, will now have one rural area with a hospital from which hospital wage data can be derived. As such, we proposed that the CY 2025 wage index for rural Delaware would be 1.0429. The final wage index for rural Delaware will be 1.0385.

The following is a summary of the comments we received on the CY 2025 HH PPS wage index and our responses:

Comment: Most commenters expressed concern with the updates to the home health wage index. Several commenters were particularly opposed to the wage index updates in rural areas. A commenter stated that utilizing hospital wage data to determine the average labor costs for rural home health agencies does not adequately reflect the costs of recruiting and retaining employees in rural settings. Another commenter stated that the current method of adjusting labor costs using the hospital wage index does not accurately account for increased travel costs and lost productivity in serving rural areas. This commenter recommended that the hospital wage index be adjusted based on population density.

Response: We appreciate commenters' concerns regarding the wage index values assigned to rural areas. As discussed in the CY 2022 HH PPS final rule (86 FR 62285), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the added cost of traveling from one patient to the next. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas. We continue to believe that in the absence of home health specific data, the pre-floor, pre-reclassified hospital wage index is appropriate for the geographic adjustment of home health claims.

Comment: Many commenters recommended far-reaching revisions and reforms to the HH PPS wage index methodology. MedPAC recommended repealing and replacing the existing HH

PPS wage index and phasing in new wage index systems for hospitals and other types of providers that uses all-employer, occupation-level wage data with different occupation weights for the wage index of each provider type; reflects local area level differences in wages between and within metropolitan statistical areas and statewide rural areas; and smooths wage index differences across adjacent local areas. Other commenters recommended discontinuing the use of the pre-floor, pre-reclassified hospital wage index as the basis for the HH PPS wage index and the creation of a home health specific wage index. Several commenters recommended allowing hospital provisions such as the area wage index policy that addresses the disparity in payments between rural and urban acute care hospitals, geographic reclassification, and an outmigration adjustment in the HH PPS wage index. Other commenters recommended that CMS institute a floor policy in the HH PPS. A few commenters recommended that CMS institute a rural floor in the HH PPS like the rural floor provided to hospitals. A few commenters recommended a 0.8000 floor in the HH PPS wage index similar to the hospice floor, while other commenters located in Puerto Rico recommended a floor of 0.6000 in the HH PPS.

Response: We thank the commenters for their recommendations. However, any updates to the home health wage index outside the proposed policies are outside the scope of the proposed rule. Changes to the HH PPS wage index would need to go through notice and comment rulemaking. Furthermore, we continue to believe that the regulations and statutes that govern the HH PPS differ from the hospital and hospice regulations and statutes, such that there would be differences between how these payment systems apply wage index policies including geographic reclassification, outmigration or the rural floor. Section 4410(a) of the Balanced Budget Act of 1997 provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that State. This rural floor provision is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Medicare Geographic Classification Review Board shall consider the application of any subsection (d) hospital

requesting the Secretary change the hospital's geographic classification for purposes of payment under the IPPS. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals.

Additionally, the application of the hospice floor is specific to hospices and does not apply to HHAs. The hospice floor was developed through a negotiated rulemaking advisory committee, under the process established by the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648). Committee members included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; consumer groups; and a government representative. The Committee reached consensus on a methodology that resulted in the hospice wage index. We continue to believe the use of the pre-floor and pre- reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the home health payment rates.

Final decision: After consideration of public comments, we are finalizing our proposal to use the FY 2025 pre-floor, pre-reclassified hospital wage index as the basis for the CY 2025 HH PPS wage index. The complete final CY 2025 wage index is available on the CMS website at https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.

4. 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 will be 74.9 percent and the non-labor-related share will 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 two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will 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 final rule, we are finalizing the implementation of a permanent adjustment of -1.975 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 final permanent adjustment factor is 0.98025. 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 final case-mix weight budget neutrality factor for CY 2025 is 1.0039.

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 final 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 final 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 0.9988. We then apply the wage index budget neutrality factor of 0.9988 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the final CY 2025 home health payment update percentage of 2.7 percent. The CY 2025 national standardized 30-day period payment rate is calculated in table 21.

TABLE 21: CY 2025 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2024 National Standardized 30-Day Period Payment	CY 2025 Permanent BA Adjustment Factor	CY 2025 Case-Mix Weights Recalibration Neutrality Factor	CY 2025 Wage Index Budget Neutrality Factor	CY 2025 Final HH Payment Update	CY 2025 National, Standardized 30-Day Period Payment
$2,038.13	0.98025	1.0039	0.9988	1.027	$2,057.35

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 final CY 2025 home health payment update percentage of 0.7 percent (2.7 percent minus 2 percentage points) and is shown in table 22.

TABLE 22: 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	CY 2025 Permanent BA Adjustment Factor	CY 2025 Case-Mix Weights Recalibration Neutrality Factor	CY 2025 Wage Index Budget Neutrality Factor	CY 2025 Final HH Payment Update Minus 2 Percentage Points	CY 2025 National, Standardized 30-Day Period Payment
$2,038.13	0.98025	1.0039	0.9988	1.007	$2,017.28

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 final 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 0.9989. As a reminder, the wage index budget neutrality factors for the national, standardized 30-

day period amount and the national LUPA per-visit rates are not equal because they are calculated differently. The wage index budget neutrality factor for the LUPA per-visit payments is calculated by simulating total payments for LUPA 30-day periods while the 30-day period budget neutrality factor is calculated by simulating payments for non- LUPA 30-day periods.

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 final CY 2025 home health payment update percentage of 2.7 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 periods that occur as the only period or initial period in a sequence of adjacent periods. The CY 2025 national per-visit rates for HHAs that submit the required quality data are updated by the final CY 2025 home health payment update percentage of 2.7 percent and are shown in table 23.

TABLE 23: CY 2025 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2024 Per-Visit Payment Amount	CY 2025 Wage Index Budget Neutrality Factor	CY 2025 Final HH Payment Update	CY 2025 Per-Visit Payment Amount
Home Health Aide	$76.23	0.9989	1.0270	$78.20
Medical Social Services	$269.87	0.9989	1.0270	$276.85
Occupational Therapy	$185.29	0.9989	1.0270	$190.08
Physical Therapy	$184.03	0.9989	1.0270	$188.79
Skilled Nursing	$168.37	0.9989	1.0270	$172.73
Speech-Language Pathology	$200.04	0.9989	1.0270	$205.22

The CY 2025 per-visit payment rates for HHAs that do not submit the required quality data are updated by the final CY 2025 home health payment update percentage of 2.7 percent minus 2 percentage points and are shown in table 24.

TABLE 24: CY 2025 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2024 Per-Visit Payment Amount	CY 2025 Wage Index Budget Neutrality Factor	CY 2025 Final HH Payment Update Minus 2 Percentage Points	CY 2025 Per-Visit Payment Amount
Home Health Aide	$76.23	0.9989	1.0070	$76.68
Medical Social Services	$269.87	0.9989	1.0070	$271.46
Occupational Therapy	$185.29	0.9989	1.0070	$186.38
Physical Therapy	$184.03	0.9989	1.0070	$185.11
Skilled Nursing	$168.37	0.9989	1.0070	$169.36
Speech-Language Pathology	$200.04	0.9989	1.0070	$201.22

We did not receive any comments on the CY 2025 30-day home health payment rates or the per-visit payment rates.

Final Decision: We are finalizing the updates to the CY 2025 national, standardized 30-day period payment rates and the CY 2025 national per-visit payment amounts as proposed, using the updated market basket amount.

d. LUPA Add-On Factors

As outlined in the CY 2025 HH PPS proposed rule, 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 described 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. At that time, we 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.

In an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, we proposed updates to 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. We proposed to use the same methodology (as specified in the CY 2025 HH PPS proposed rule) used to establish the LUPA add-on amount for CY 2014, using updated claims data.

Specifically, we proposed 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 the CY 2025 HH PPS proposed rule (89 FR 55377), using the CY 2023 data available at that time, the proposed updates to the factors were 1.7227 for SN; 1.6247 for PT; and 1.6703 for SLP. We stated that the proposed LUPA add-on factors will be updated based on more complete CY 2023 claims data in the final rule. The updated analysis (as of September 11, 2024) 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 29.91 minutes for the first

visit if SN, 28.08 minutes for the first visit if PT, and 31.57 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes are 41.54 minutes for SN, 45.11 minutes for PT, and 47.15 minutes for SLP. To determine the LUPA add-on factors for each discipline in relation to the final 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 final add on factors: 1.7200 for SN; 1.6225 for PT; and 1.6696 for SLP. We solicited comments on the proposals to update the LUPA factors using the CY 2014 methodology and the re-priced LUPA payment amounts. A summary of these comments and our responses are as follows:

Comment: All commenters expressed support for updates to the LUPA add-on factors for skilled nursing, physical therapy and speech language pathology using CY 2023 utilization data using the CY 2014 HH PPS methodology. Specifically, commenters expressed appreciation that CMS still recognizes LUPA per visit payments.

Response: We thank the commenters for their support.

Comment: A commenter expressed support for CMS' efforts to adjust the LUPA add-on factor but noted that the adjustments remain minimal and are not adequately aligned with inflationary trends.

Response: We thank the commenter for their comment. The LUPA add-on factors were adjusted in a budget neutral manner, as statutorily required in section 1895(b)(3)(A)(i) of the Act, so that aggregate payments do not increase or decrease.

Final Decision: We are finalizing the proposal to update the SN, PT, and SLP LUPA add-on factors. The final LUPA add-on factors are 1.7200 for skilled nursing, 1.6225 for physical therapy, and 1.6696 for speech-language pathology.

e. Occupational Therapy LUPA Add-On Factor

As outlined in the CY 2025 HH PPS proposed rule, in order to implement Division CC, section 115, of the Consolidation Appropriations Act (CAA), 2021, CMS finalized changes to

the 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 a policy using the PT LUPA add-on factor as a proxy. We also stated in the CY 2022 final rule that we will 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 the proposal.

With sufficient recent claims data available, and to establish equitable compensation for all home health services, CMS proposed 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 the proposal, we used 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 updated the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. The originally proposed analysis showed 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 as 33.40 minutes for the first visit and the average number of minutes for all non-first visits in non-LUPA periods as 45.97 minutes for OT. However, the proposal was made using the most current and complete data available at the time of rulemaking. We stated that we believe that LUPA add-on factors will be updated based on more complete CY 2023 claims data in the final rule. In doing so, the updated analysis (as of September 11, 2024) 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 33.28 minutes for the first visit. The average number of minutes for all non-first visits in non-LUPA periods is 45.98 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 proposed 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 proposed to then add one to this ratio to obtain the proposed add on factor: 1.7238 for OT.

The following table 25 shows, for all disciplines, 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 final LUPA add-on factors (using updated CY 2023 claims data), and the percent change between the current and the final LUPA add-on factors.

TABLE 25: CURRENT AND FINAL LUPA ADD-ON FACTORS FOR ALL DISCIPLINES

Discipline	Current LUPA Add-on Factors	Final 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	1.7200	-6.8%	29.91	41.54
PT	1.6700	1.6225	-2.8%	28.08	45.11
SLP	1.6266	1.6696	+2.6%	31.57	47.15
OT	1.6700	1.7238	+3.2%	33.28	45.98

We solicited comments on the proposed establishment of a definitive OT LUPA add-on factor, use of CY 2023 data to determine the OT LUPA add-on factor, as well as the proposed methodology to determine this OT LUPA add-on factor. A summary of these comments and our responses are as follows:

Comment: All commenters expressed support for establishment of the definitive LUPA add-on factor for occupational therapy using CY 2023 utilization data and the CY 2014 HH PPS methodology.

Response: We thank the commenters for their support.

Comment: A commenter expressed appreciation for CMS' recognition of the unique needs of OT services through the establishment of a distinct OT LUPA add-on factor. However, they voiced concern that the current add-on factor does not fully address the challenges faced by occupational therapists, particularly in light of payment rate reductions. As such, the commenter recommended that CMS continuously evaluate and adjust the OT add-on factor.

Response: We thank the commenter for their comment. However, the payment rate adjustment was made to the 30-day base payment rate and the OT LUPA add-on factor was established in a budget neutral manner, as statutorily required in section 1895(b)(3)(A)(i) of the Act. We will update the LUPA add-on factors as necessary in accordance with applicable regulations.

Comment: Many commenters raised concerns regarding proposed payment rate reductions specific to occupational therapy services, specifically stating that proposed payment cuts to occupational therapy could significantly reduce access to essential occupational therapy services for Medicare beneficiaries receiving care at home.

Response: We appreciate the commenters' concern. It appears that many commenters conflated the OT LUPA add-on factor proposal with the proposed permanent adjustment to the national, standardized 30-day payment rate. To clarify, in the CY 2025 HH PPS proposed rule (89 FR 55377) we did not propose any OT-specific payment rate cuts. In fact, with the proposal

to establish a definitive OT LUPA add-on factor and discontinue the use of the PT LUPA add-on factor as a proxy, the add-on factor for OT services has increased by 3.2 percent.

Final Decision: We are finalizing the proposal to discontinue use of the PT LUPA add-on factor as a proxy and establish the definitive LUPA add-on factor for occupational therapy to be used in calculating the LUPA add-on payment amounts. The OT LUPA factor is 1.7238 when occupational therapy is the first skilled visit in a LUPA period that occurs as the only period or an initial period in a sequence of adjacent periods.

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 will 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 will 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 will 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) 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 proposed an FDL ratio of 0.38 for CY 2025 which is higher than the finalized CY 2024 FDL of 0.27. We stated that we would update the FDL, if needed, in the final rule once we have more complete CY 2023 claims data. Therefore, using updated CY 2023 claims data as of (July 11, 2024) the final FDL ratio for CY 2025 is 0.35.

A summary of the comments we received on the proposed FDL ratio appears as follows.

Comment: A commenter opposed the estimated 0.6 percent decrease to home health payments which is the result of increasing the fixed-dollar loss ratio for outlier payments in CY 2025. The commenter stated that that the 0.6 percent decrease should be eliminated as there is not adequate data to surmise that the cut is justified.

Response: We thank the commenter for their comment. However, we disagree with the claim that there is not adequate data to justify the 0.6 percent decrease. We are statutorily required to ensure that total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). 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 the PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day periods of care. We have used the most recent claims data to calculate the FDL ratio since that time. In the CY 2025 HH PPS proposed rule, we stated that we would use the most recent claims data available which is CY 2023 claims data. Using CY 2023 claims data, we found that the FDL ratio would need to be increased from the final CY 2024 FDL of 0.27 to the proposed CY 2025 ratio of 0.38. A higher FDL ratio reduces the number of periods that can receive outlier payments, and as a result there is a slight decrease to total payments. Based on more complete CY 2023 claims data as of (July 11, 2024) the final CY 2025 FDL ratio has been adjusted to 0.35 which results in a 0.4 percent decrease in total payments.

Final Decision: We are finalizing the CY 2025 FDL ratio of 0.35, using updated CY 2023 claims data as of July 11, 2024.

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 will 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 (type of bill (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, will 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 a dNPWT Device

For CY 2025, we proposed 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 noted that the CPI–U for the 12-month period ending in June of 2024 was not available at the time of the proposed rulemaking and stated that 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 would be updated in the final rule.

For this final rule, the CPI–U for the 12-month period ending in June of 2024 is 3.0 percent and the corresponding productivity adjustment is 0.6 percent based on IHS Global Inc.'s third-quarter 2024 forecast of the CY 2025 productivity adjustment (which reflects the 10-year moving average of changes in annual economy-wide private nonfarm business TFP for the period ending June 30, 2024) Therefore, the final update percentage will be 2.4 percent (3.0 percent reduced by 0.6 percentage point). The final CY 2025 separate payment amount for a dNPWT device will be $276.57, which reflects the CY 2024 payment amount of $270.09 updated by the final update percentage of 2.4 percent.

CY 2025 Disposable Negative Pressure Wound Therapy Rate (dNPWT)		
CY2024 dNPWT Payment Rate	**CY2025 dNPWT Payment Update (12-month CPI-U ending in June 2024 (3.0%) Reduced by Productivity Adjustment (0.6%))**	**CY2025 dNPWT Payment Rate**
$270.09	1.024	$276.57

The following is a summary of the public comments and our responses regarding the payment update for the dNPWT device.

Comment: A commenter recommended that stakeholders be given the opportunity to comment on the final payment amount for dNPWT in the event there is an issue in the calculation of the rate.

Response: We thank the commenter for their recommendation. However, we stated in the proposed rule that the CPI-U and productivity adjustment were not available in time for the publication of the proposed rule and the rate would be published in the final rule. Although the final rate was not available at the time of the proposed rule, in the CY 2025 HH PPS final rule (89 FR 77751), we finalized the policy of setting the separate payment of a dNPWT device equal to the payment amount established for the device in the previous year, updated by the percentage increase in the CPI–U reduced by the productivity adjustment for the 12-month period ending in June of the previous year. The CY 2025 final rule simply updates the dNPWT device separate payment amount using this finalized policy. As such, we believe there was adequate opportunity for commenters to provide feedback on the calculation of the final CY 2025 rate. If we are alerted to an issue in the calculation of this final rate after publication of this final rule, we would issue a correction notice if necessary.

Comment: A commenter stated that while they recognize that changes to the dNPWT device separate payment amount were required by statute, they believe that the payment approach for dNPWT devices is confusing and adds another level of burden for HHAs. This commenter recommended that dNPWT be removed from the HH PPS payment structure entirely and be independently paid through the durable medical equipment (DME) benefit. The commenter suggested that making this change would help ensure that Medicare beneficiaries receive appropriate wound care, and providers receive fair and equitable payment for supplies and related services.

Response: We appreciate the commenter's recommendation. However, this comment is outside the scope of the proposed rule. We are statutorily required to process claims for the separate payment amount of an applicable dNPWT device on claims submitted using the type of bill (TOB) 32X, and the payment rate for dNPWT under the home health benefit is described in statute. Furthermore, dNPWT devices are disposable, thus would not be eligible for payment under the DME benefit. Therefore, the separate payment amount for dNPWT devices will continue to be reported on the home health TOB 32X using HCPCS code A9272 (for the device only). As a reminder, 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.

Final Decision: We are finalizing the CY 2025 separate payment amount for the dNPWT device under a home health plan of care of $276.57, which is equal to CY 2024 rate of $270.09 updated by the final update percentage of 2.4 percent. 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 2022, CMS tested a shortened survey across a variety of different types of HHAs. We reviewed the findings of the field test and plan to finalize in the future updates to the survey with the intent to shorten it. Potential updated HHCAHPS measures have been submitted through the Pre-rulemaking Review Process.

B. Summary of the Provision of this Final Rule

In this final rule, we are finalizing the proposal to add four new assessment items and modify one assessment item on the OASIS. Second, we are finalizing an update to the removal of the suspension of OASIS all-payer data collection. Third, we sought 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 19 measures for the CY 2024 program year, as described in table 26.

TABLE 26: 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 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).[2]
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**
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (CBE #3477)
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.

[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.

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 final rule, we have added four new items[12] 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 modified the current "Transportation" item collected as standardized patient assessment data under the SDOH category as described in section III.D.5. of this final 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). Section 1899B(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: (i) functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider; (ii) cognitive function, such as ability to express ideas and to understand, and mental status, such as depression and dementia; (iii) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (iv) medical conditions and comorbidities, such as diabetes, congestive heart failure,

[12] Items may also be referred to as "data elements."

and pressure ulcers; (v) impairments, such as incontinence and an impaired ability to hear, see, or swallow; and (vi) 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.[13] 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.[14] 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.[15,16,17] This expanded definition aligns our definition of SDOH with the definition used by other HHS agencies, including Office of the Assistant Secretary for Health (OASH), the Centers for Disease Control and Prevention (CDC) and the White House Office of Science and Technology Policy

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[13] 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.

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

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

[16] 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.

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

(OSTP).[18,19] 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.[20] 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 proposed to be collected as standardized patient assessment data elements under the SDOH

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[18] Centers for Disease Control and Prevention. Social Determinants of Health (SDOH) and PLACES Data.
[19] "U.S. Playbook to Address Social Determinants of Health" from the White House Office of Science and Technology Policy (November 2023).
[20] 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).

category in this rule were also identified in the 2016 NASEM report[21] or the 2020 NASEM report[22] 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 able 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.[23] 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.[24,25] Certain HRSNs can lead to unmet social needs that directly influence an individual's physical, psychosocial, and functional status.[26] This is particularly true for food security, housing stability, utilities security, and access to transportation.[27] Evidence supports the positive impact on health outcomes of interventions aimed at addressing HRSNs.[28]

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[21] Social Determinants of Health. Healthy People 2020. https://www.cdc.gov/nchs/healthy_people/hp2020.htmFebruary 2019.
[22] 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/10.17226/25682.
[23] 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.
[24] 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.
[25] 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.
[26] 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/*.
[27] 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/*.
[28] 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

We proposed 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 will collect information not already captured by the current SDOH items. Specifically, we believe the ongoing identification of SDOH will have three significant benefits. First, promoting SDOH screening could serve as evidence-based building blocks for supporting healthcare providers in actualizing their commitment to address disparities that disproportionately impact underserved communities. Second, SDOH screening advances health equity through identifying potential social needs so that an HHA may address those with the patient, their caregivers, and community partners during the home health episode and discharge planning process, if indicated.[29] Third, these SDOH items will support ongoing HH QRP initiatives by providing data to stratify HHAs' performance on current and future quality measures to improve care quality across different populations.

Additional collection of SDOH items will 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.[30] We

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Planning and Evaluation) Office of Health Policy. Report HP-2022-12 April 1, 2022. SDOH-Evidence-Review.pdf (hhs.gov). Accessed 5/29/2024.

[29] 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.*

[30] 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.

note that advancing health equity by addressing the health disparities that underlie the country's health system is one of our strategic pillars[31] and a Biden-Harris Administration priority.[32]

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[33]

We proposed to require that 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 section III.D.3.a. of this final rule; two items for food, as described in section III.D.3.b. of this final rule; and one item for utilities, as described in section III.D.3.c of this final rule.

We selected the final 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.[34,35] 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

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[31] 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.*

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

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

[34] 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.

[35] 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.

needs; and (5) interpersonal safety concerns (for example, intimate-partner violence, elder abuse, child maltreatment).[36]

We believe that requiring HHAs to report new items that are currently included in the AHC HRSN Screening Tools will further standardize the screening of SDOH across patient assessment instruments and the various quality reporting programs. For example, our proposal will 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.[37] Beginning January 2025, inpatient psychiatric facilities (IPFs) will also be required to report whether they have screened patients for the same set of SDOH categories.[38] 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.[39,40] 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.[41] These experiences may negatively affect physical health and make it

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[36] More information about the AHC HRSN Screening Tool is available on the website at *https://innovation.cms.gov/Files/worksheets/ahcm-screeningtool.pdf*.
[37] Centers for Medicare & Medicaid Services, FY2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49194).
[38] Centers for Medicare & Medicaid Services, FY 2024 Inpatient Psychiatric Prospective Payment System – Rate Update (88 FR 51107 through 51121).
[39] https://health.gov/healthypeople/priority-areas/social-determinants-health.
[40] Healthy People 2030 is a long-term, evidence-based effort led by the HHS that aims to identify nationwide health improvement priorities and improve the health of all Americans.
[41] 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

harder to access health care. Lack of housing stability can also lead to homelessness, which is housing deprivation in its most severe form.[42] 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.[43] Rates of chronic disease and premature mortality are higher among the unsheltered homeless relative to the sheltered.[44] 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.[45] Adults (aged 18 – 64 years) with disabilities experience challenges to securing stable housing including affordability and accessibility.[46] 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

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[42] 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.

[43] 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.

[44] 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.

[45] 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.

[46] 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.

and follow-up.[47] 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 will allow patients' additional resources to be allocated towards housing without sacrificing other needs.[48] 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 proposed 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[49,50] and was adapted from the Protocol for Responding to and Assessing Patients' Assets, Risks, and Experiences (PRAPARE) tool.[51] 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 webpage at https://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

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[47] 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.

[48] 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.

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

[50] 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.

[51] 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/.

access to adequate food.[52] 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.[53] 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."[54] While having enough food is one of many predictors for health outcomes, a diet low in nutritious foods is also a factor.[55] 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.[56] 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.[57] HHAs could also refer any patient that indicates lack of food

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[52] 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/.

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

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

[55] 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.

[56] 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.

[57] 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.

security to government initiatives such as home delivered meals programs provided by Area Agencies on Aging,[58] 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.[59]

We proposed 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).[60] The first proposed Food item states: "Within the past 12 months, you worried that your food will 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 webpage 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.[61] According to the Department of Energy, one in three households in the U.S. are unable to adequately meet basic household energy needs.[62] The median energy

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

[59] 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.

[60] 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/.

[61] 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.

[62] 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/.

burden for rural households of older adults is considerably higher than that for households without older adults.[63] 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.[64] 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.[65] 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.[66] The effects of a lack of utility security include vulnerability to environmental exposures such as dampness, mold, and thermal discomfort in the home, which have direct effect on patients' health.[67] 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.[68] We believe adopting an item to collect

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[63] 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.

[64] 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.

[65] 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.

[66] 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/.

[67] 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.

[68] 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.

information about a patient's utility security upon start or resumption of care in HHAs will 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)[69] or receive broadband Internet service through the Affordable Connectivity Program.[70] 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.[71]

We proposed to adopt a new Utilities item 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.[72] 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 webpage at https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures.

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

[70] https://www.fcc.gov/broadbandbenefit.

[71] 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.

[72] 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.

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 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 the proposal.

We invited 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.

Comment: The majority of commenters supported the proposal. Supportive comments noted the importance and relevance of SDOH to home health and the importance of interoperability. Some commenters noted that their home health agencies are already collecting this information and have established community partnerships to address SDOH.

Response: CMS appreciate commenters' support for the proposal and agrees that SDOH are important and relevant to home health. CMS also agrees that interoperability is important to measure quality and advance health equity, and thus we propose data elements that are standardized across the PAC settings. CMS appreciates that some home health agencies are already addressing SDOH by collecting information and working with community partners.

Comment: Some commenters expressed support for the proposal and suggested changes, including expanding the assessment to capture overall financial need, and embedding the American Healthy Communities (AHC) screening tool in the assessment instruments. One commenter suggested that CMS require collection of the information but not specify the tool or instrument to be used.

Response: CMS appreciates the commenters' suggestions and acknowledge that patients' overall financial need and other data elements from the AHC screening tool are important. However, the proposed data elements have been identified 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 enable HHAs to offer assistance, by connecting patients and their caregivers with these associated needs to social support programs, as well as inform our understanding of the level of patient clinical complexity. We believe the proposed data elements offer the greatest potential benefit without undue burden for patients and HHAs.

Comment: Commenters that supported the proposal also expressed implementation concerns that vendors be provided enough time to prepare for the changes; that home health agencies be provided time and resources to educate staff on the changes; that OASIS revisions are too frequent and burdensome for agencies; and that implementation of the proposal would be burdensome. Some commenters cautioned that SDOH needs identified must be addressed, and one suggested that CMS should provide additional reimbursement to HHAs for the follow-up required to address identified needs.

Response: CMS acknowledges and appreciates the commenters' concerns and suggestions. CMS is finalizing the SDOH data elements in this CY2025 final rule with an effective date of January 1, 2027, to ensure that vendors and HHAs have sufficient time to prepare for implementation of data collection. CMS will make training available to HHAs on the changes to the OASIS, consistent with education and training resources for previous revisions to the OASIS instrument. CMS acknowledges that revisions to the OASIS require that providers expend time, effort, and resources to prepare for the changes. CMS is committed to proposing revisions to the OASIS no more frequently than every two years. CMS agrees that patients' needs should be addressed by the HHA, consistent with applicable rules and regulations,

although we note that the proposal does not specify a requirement for how HHAs may address patients' needs.

Comment: A commenter suggested that CMS consider home health SDOH data differently than data from the PAC institutional settings, noting that in home health, an HHA staff member often walks into the home where a situation caused by or related to one or more SDOH is already happening and may be at a crisis level. In those situations, HHAs may not have the capacity to remediate identified issues since this would take significantly more time than merely conducting the assessment. The commenter suggested that requirements that HHA staff respond to patient and caregiver crises may trigger obligations such as mandatory reporting to the local adult protective services agency, or requiring that the staff member call county health officials to condemn a patient's current living space even when no housing alternative exists. These requirements would violate the trust the HHA is trying to establish through its services and jeopardize individuals' ability to access needed services for which they are eligible. The commenter suggests that the SDOH data elements not be used as process or outcome measures without additional CMS support for HHAs and recommends that the SDOH data elements be considered an opportunity to gather more information on populations accessing home health services.

Response: CMS acknowledges that the home health setting differs from that of the institutional PAC settings. However, we believe that HHAs can benefit from this information to facilitate coordinated care, improve patient focused care planning, and allow for continuity of the discharge planning process. Ultimately, CMS believes that first, 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 of individuals 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.[73] Third, these SDOH items will 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.

Comment: Commenters that did not support the proposal acknowledged that SDOH information was important, but stated that adding four data elements to the OASIS and modifying a fifth would be burdensome. One commenter noted that revisions to the OASIS are too frequent and recommended that CMS limit revisions to intervals of no less than four years. One commenter suggested that the proposed "living situation" data element duplicates other information that is already collected, and recommended that the look-back for the "utilities" data element be changed from 12 months to three to capture more reliable, valid, and timely information. Another commenter encouraged CMS to consider using SDOH information as part of the risk-adjustment of outcome quality measures. A commenter stated the proposal is not aligned with health-related social needs reporting requirements across the care continuum and that further testing and refinement are needed to ensure the proposed items work as intended in this setting. This commenter noted the proposed data elements are not standardized with those in the Inpatient and Inpatient Psychiatric Facility Quality Reporting Programs, so are not interoperable, and also noted that inpatient psychiatric facilities may use any standardized health-related social needs screening tool. This commenter noted that CMS' evaluation of the AHC HRNS screening tool in the AHC Model showed that screening did not appear to increase beneficiary connection to community resources or health-related social need resolution, and they recommended that CMS conduct further testing and develop clearer implementation guidance before adopting the proposed data elements in the HHQRP. This commenter also requested that CMS articulate its vision for how the health-related social need information collected by the

[73] 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.*

proposed data elements would be used in its quality and payment programs, noting for example that measures holding HHAs accountable for community-based outcomes such as connection to community resources and resolution of health-related social need is outside the scope of covered home health services as defined by Medicare.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. As previously stated, CMS acknowledges that revisions to the OASIS require HHAs' time, effort, and resources, and we are committed to proposing revisions to the OASIS no more frequently than every two years. CMS disagrees that the proposed "Living Situation" data element duplicates information that is already collected because it addresses housing insecurity, which is not part of the information captured in the current OASIS. CMS appreciates the suggestion to reduce the look-back period for the "Utilities" data element and will take this into consideration as we review data submitted. CMS acknowledges that the SDOH data elements finalized in this rule are not aligned with those of the inpatient QRPs; however we believe that standardization across the PAC settings is an important step in advancement towards interoperability. CMS believes that the data elements finalized in this rule are not setting-specific, and that the testing conducted in their development has been sufficiently rigorous that we can adopt the data elements into the OASIS and the other PAC instruments with confidence.

After consideration of the public comments we received, we are finalizing our proposal to adopt four new items as standardized patient assessment data elements under the SDOH category beginning with the CY 2027 HH QRP.

5. Modification of 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 will 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 proposed 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. Data element A1250, "Transportation", currently collected in the OASIS asks patients: "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". By comparison, 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 proposed 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 use 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 proposed 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 ways, including accessing goods and services, obtaining adequate food and clothing, and social activities.[74] The proposed modified "Transportation" item will 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 proposed to modify the current 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 webpage at https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures/downloads.

[74] 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.

We invited comment on the 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.

Comment: Most commenters supported the modification of the "Transportation" item to align with the AHC HRSN Screening Tool. Some even suggested adopting more components of the AHC tool to the OASIS assessment tool.

Response: CMS appreciate commenters' support for the proposal and agrees that the adoption of this AHC item improves consistency with other provider settings.

Comment: A few commenters noted a concern related to the burden required to update the OASIS with the replacement of the current "Transportation" item.

Response: CMS acknowledges there is a change to the OASIS that will be required with the modification of the "Transportation" item but there will be sufficient guidance to clarify the correct completion of the new item. Additionally, the new item does not substantially increase effort in completing the OASIS tool relative to the current "Transportation" item.

After consideration of the public comments we received, we are finalizing our 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 will 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 will start but did not address the other data collection time points.

To clarify expectations around the start of OASIS all-payer data collection we proposed 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 HHA characteristics (for example, Agency's CMS Certification Number (CCN), State and Branch ID#s) and patient-specific information (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 will ensure that baseline data is available for use in calculating or risk-adjusting quality measures, and in linking to prior OASIS assessments. The data will 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.[75] 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

[75] www.congress.gov/108/statute/STATUTE-117/STATUTE-117-Pg2066.pdf.

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 invited comment on the proposal to update requirements for OASIS all-payer data collection beginning January 1, 2025.

Comment: Those who supported the proposal emphasized that a voluntary phase-in and the use of the start of care date to initiate all payer submission would provide consistency with how the policy is implemented. Another commenter noted the resumption of all payer OASIS data collection and submission aligns policies and reporting across post-acute care settings and patient subsets and provides a fuller, more accurate representation of home health quality of care for use in beneficiary health care decision making, policy development, and health services research.

Response: CMS thanks commenters for providing feedback on the proposal. The goal of implementing all-payer data collection and submission is to facilitate a better understanding of quality of care provided to patients in Medicare-certified home health and post-acute care settings in general, regardless of payor source.

Comment: Some commenters acknowledged the importance of OASIS all-payer data but expressed concerns about how CMS will use the data in the HHQRP and the HHVBP.

Response: CMS acknowledges concerns about how the data collected with the implementation of all-payer data collection and submission will be utilized. CMS expects to use this data to gain a better understanding of the overall quality of care provided by Medicare-certified providers and the patients they serve, regardless of payor source.

Comment: Some commenters raised questions about how the all-payer policy would be implemented for patients without any payor source and in other scenarios such as how to complete OASIS for non-Medicare patients already on service, or that transfer to the hospital, or

for payer changes. One commenter asked about whether PDGM rules for a 60-day episode and 30-day payment period apply to all payers.

Response: CMS thanks commenters for the questions regarding implementation of all-payer data collection and submission. All-payer data collection and submission is intended for any patient receiving skilled home health care service that would meet requirements for an OASIS assessment. As noted in the proposal, data collection at time points outside of start of care for patients already on home health care service before the implementation of mandatory all-payer data collection and submission will not be required. The implementation of mandatory all-payer data collection and submission is also not intended to impact payment policy.

Comment: Another commenter expressed concern about the implications for patient privacy, particularly for patient care funded by non-government payers.

Response: CMS acknowledges privacy concerns with the implementation of the all-payer data collection and submission. Data security and patient privacy are priorities for CMS. CMS intends to follow all Federal guidelines related to data security and patient privacy.

Comment: Commenters who opposed the proposal most often raised the issue of the burden of implementing the new policy. One commenter noted that deep labor shortages, particularly for nurses and home health aides, would impact availability of staff to meet the expanded data collection requirement. Some raised concerns about the new policy's effect on reimbursement and that completing all required home health admissions could become more difficult.

Response: Related to the concern about burden, as noted when the all-payer data collection policy was first proposed, CMS expects that the six-month voluntary submission period will allow providers the time and experience to effectively implement the new policy. As clinical assessment of all patients is an important standard, CMS anticipates the OASIS assessment will replace other assessment tools currently in place for non-Medicare/Medicaid payor sources.

After consideration of the public comments we received, we are finalizing our proposal to update requirements for OASIS all-payer data collection beginning January 1, 2025.

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 final rule, we proposed 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 rule beginning January 1, 2027, with the CY 2027 HH QRP.

We proposed that HHAs will 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 will 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 also proposed that HHAs that submit the living situation, food, utilities, and transportation items with respect to start or resumption of care will 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 webpage at https://www.cms.gov/medicare/quality/home-health/home-health-quality-measures. As we noted in section III.D.5 of this final 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 invited 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 final rule; two Food items, as described in section III.D.3.b of this final rule; one Utilities item as described in section III.D.3.c of this final rule; and one "Transportation" item as described in section III.D.5 of this final rule.

A majority of commenters supported the proposal. Supportive comments included that SDOH are important and relevant to home health, and that interoperability is important. Some commenters noted that their home health agencies are already collecting this information and have established community partnerships to address SDOH.

Response: CMS appreciate commenters' support for the proposal and agrees that SDOH are important and relevant to home health. CMS also agrees that interoperability is important to measure quality and advance health equity, and thus we propose data elements that are standardized across the PAC settings. CMS appreciates that some home health agencies are already addressing SDOH by collecting information and working with community partners.

Commenters that supported the proposal expressed concerns about implementation including that the vendors be provided enough time to prepare for the changes, that home health agencies be provided time and resources to educate staff on the changes, that OASIS revisions

are too frequent and burdensome for agencies and that implementation of the proposal would be burdensome. Some commenters cautioned that SDOH needs identified must be addressed, and one suggested that CMS should provide additional reimbursement to HHAs for the follow-up required to address identified needs.

Response: CMS acknowledge the commenters' concerns and appreciate their suggestions. CMS is proposing the SDOH data elements in the CY 2025 HH PPS proposed rule with an effective date to begin collection via the OASIS instrument of January 1, 2027, to ensure that vendors and HHAs have sufficient time to prepare for implementation. CMS will make training available to HHAs on the changes to the OASIS, consistent with education and training resources for previous revisions to the OASIS instrument. CMS acknowledges that revisions to the OASIS require time and effort and resources for providers to prepare for the changes and is committed to proposing revisions to the OASIS no more frequently than every two years. CMS agrees that patients' needs should be addressed by the HHA, consistent with applicable rules and regulations, although we note that the proposal does not specify a requirement for how HHAs may address patients' needs.

Commenters that did not support the proposal acknowledged that SDOH information is important but adding four data elements to the OASIS and modifying a fifth would be burdensome. One commenter noted that revisions to the OASIS are too frequent and recommended that CMS limit revisions to intervals of no less than four years. One commenter suggested that the proposed living situation data element is duplicative of information that is already collected and recommended that the look-back for the utilities data element be changed from 12 months to three to capture more reliable, valid, and timely information. Another commenter encouraged CMS to consider using SDOH information as part of the risk-adjusted outcome quality measures. A commenter stated the proposal is not aligned with health-related social needs reporting requirements across the care continuum and that further testing and refinement are needed to ensure the proposed items work as intended in this setting. This

commenter noted that CMS' evaluation of the AHC HRNS screening tool in the AHC Model showed that screening did not appear to increase beneficiary connection to community resources or health-related social need resolution, and they recommended CMS conduct further testing and developing clearer implementation guidance before adopting the proposed data elements in the HHQRP.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. As previously stated, CMS acknowledges that revisions to the OASIS require time and effort and resources for providers to prepare for the changes and we are committed to proposing revisions to the OASIS no more frequently than every two years. CMS disagrees that the proposed Living Situation data element is duplicative of information that is already collected because it addresses housing insecurity, which is not part of the information captured in the current OASIS. CMS believes that the proposed data elements are not setting-specific, and that the testing conducted in their development has been sufficiently rigorous that we can adopt the data elements into the OASIS and the other PAC instruments with confidence.

After consideration of the public comments we received, we are finalizing our proposal 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 rule beginning January 1, 2027, with the CY 2027 HH QRP.

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

We sought 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) (CY 2024 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 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.[76] The TEP discussed the alignment of PAC and Hospice measures with CMS' "Universal Foundation" of quality measures.[77] 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,[78] which could represent overall immunization status of patients such as the Adult Immunization Status measure[79] in the Universal Foundation. A second concept on which we sought feedback is the concept of depression for the HH QRP, similar to the Clinical Screening for Depression and Follow-up measure[80] in the Universal Foundation. Third, we sought feedback on the concept of pain management. Finally, we seek input on a measure concept

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[76] 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*.

[77] 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

[78] 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.

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

[80] 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.

relating to substance use disorders, such as the Initiation and Engagement of Substance Use Disorder Treatment measure[81] included in the Universal Foundation of Quality Measures.

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

1. Composite Vaccination Concept

Some commenters supported a composite vaccination measure concept, while most commenters did not support this concept. Commenters in support of this measure concept noted that the measure would support increased immunization rates. One commenter noted that a composite vaccination measure would help bring vaccinations to homebound individuals, reducing access barriers, and may encourage home health agencies to have conversations with vaccine-skeptical individuals to share the benefits of vaccinations in general or one specific vaccination. This commenter went on to suggest that a focus on overall vaccination status is necessary for beneficiaries who may have long term health needs, chronic conditions and vulnerability to infection and disease. Lastly, the commenter suggested that a holistic approach is more equitable in that it can ensure individuals from all backgrounds are more likely to get a comprehensive set of vaccines. Several commenters expressed concerns about a composite vaccination concept, despite supporting this as a measure concept. One suggested that CMS revise the way rates are measured and reported so that, for example, a percentage of beneficiaries who are offered a vaccination does not convey a false impression of success. Another commenter suggested that CMS should ensure vaccines and combination products are accessible to providers and beneficiaries, and noted that home health agencies may have issues finding information on beneficiary vaccination status, nurses may not have time to administer vaccines, vaccines are costly to home health agencies, and that transport of vaccines requiring cold-chain and storage

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

may present operational problems for home health staff who must spend hours a day on the road. Among the commenters that did not support a composite vaccination concept, most shared additional details. Most noted that such a measure would be burdensome to home health agencies because patient recall may be unreliable, so the home health agencies who do not have ready access to information about patients' vaccination status would have to conduct extensive review of patient's medical records to find this information. Some commenters referred to the December 2023 Post-Acute Care (PAC) and Hospice Quality Reporting Program Technical Expert Panel, noting that many provider participants did not support a vaccination measure concept. One commenter suggested patients might consider their vaccination status sensitive information and be hesitant to share their status with the home health staff. One commenter noted multiple issues home health agencies might encounter in implementation of such a measure including the expense of vaccines, and of ensuring safe vaccination of homebound patients, and the expense of controls and equipment needed to maintain compliance with controlled temperature chains required for vaccines, and that once a vial is opened the entire vial needs to be used in a specified short time frame that home health providers may not be able to achieve, thus wasting multiple doses. A final concern this commenter expressed was that providers who served populations who believe in vaccination would have an advantage over providers who serve populations with vaccine hesitancy.

2. Depression Concept

The majority of commenters supported the depression measure concept, with one commenter noting that home health already collects this data, and another commenter noting that patients who need home healthcare may be more likely to develop depression due to their diagnoses, chronic pain or lack of independence, and that identifying risk early and implementing interventions can improve patient outcomes and quality of life. A commenter noted that depression can affect patients' ability to care for themselves and provided the example of evidence-based occupational therapy interventions to directly impact depression such as

engaging patients in activities that promote participation in everyday life, which can help build resilience, positive psychological and social functioning and the ability to adapt to change and cope with life challenges.

Some commenters did not support the measure concept for depression. One commenter noted that home health clinicians already complete the Patient Health Questionnaire – 9 (PHQ-9) and are responsible for follow-up with the provider for patients that screen positive. Several commenters pointed out that home health agencies are limited in options or are not set up to address depression. A few commenters noted in addition that significant resources and infrastructure would be required for home health agencies to address depression, and that home health patients are often discharged before any outcomes from community referrals can be realized. These commenters also suggested that home health would be limited to a referral to the patient's primary care physician for further interventions, noting that home health agencies cannot be expected to provide interventions aimed at directly treating depression, such as pharmacological interventions or other follow-up that involves long-term planning.

3. Pain Management Concept

Comments in support of a pain management measure concept mentioned the relevance of pain management for home health, and the impact pain has on all aspects of patients' lives. Several commenters noted that CMS retired a pain management measure from the HHQRP in 2020 due to the opioid crisis and suggested that, given this context, clarification about the intent of reintroducing this type of measure would be helpful.

4. Substance Use Disorders Concept

Some commenters expressed support for the substance use disorder (SUD) measure concept, while most did not support this concept. One commenter shared that their home health agency has been seeing more patients with this condition, noting that generally this population is rejected by home health agencies due to increased risk of hospitalization and the tendency not to make progress quickly. The commenter encouraged CMS to explore collection of SUD

information and use of this information for risk-adjusted payments that would support additional home health resources. Most commenters did not support the SUD concept, with most of those who do not support going on to note that management of SUD disorders is out of scope for home health or that home health agencies are not set up to manage SUD, which requires specially trained clinicians. One of these commenters noted that because there is no data source currently available, adding a SUD measure would add burden to home health agencies.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to the RFI in this final rule, we intend to use this input to inform 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 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.[82] 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 will further reduce Medicare spending and improve the quality of care. In October 2020, the CMS Chief Actuary certified that expansion of the HHVBP Model will produce Medicare savings if expanded to all States.[83]

[82] https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.
[83] https://www.cms.gov/files/document/certificationhome-health-value-based-purchasing-hhvbpmodel.pdf.

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.[84]

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.[85] 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.

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

[85] 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.

● 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.[86] Creating one or more measures based on an HHA's ability to meet caregiver needs will permit measurement of changes in caregiver quality-of-life.

● *Falls with major injury (claims-based)*: Several TEP members suggested that CMS explore a claims-based measure of falls with major 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.[87] 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 will only be available for Fee for Service patients. Due to the high rate of non-reporting, the OASIS-based falls measure may not provide accurate information about the incidence of these falls.

● *Medicare Spending per Beneficiary (MSPB)*: 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 will provide

[86] For more details on the GUIDE Model, see the Model webpage (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).
[87] https://oig.hhs.gov/oei/reports/OEI-05-22-00290.asp.

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 requested comments related to adding the potential performance measures described previously to the HHVBP Measure Set. We also requested comments about other potential performance measures that we should consider for the expanded HHVBP Model.

We received the following comments:

Comments: We received generally positive stakeholder reaction to the request for information on future measure concepts for the expanded HHVBP Model. Commenters also expressed concerns about each of the potential measures.

Commenters were generally supportive of the caregiver burden assessment measure concept, but expressed concerns about how to accurately identify caregivers, how the data would be utilized, and whether the data would be used to determine home care eligibility.

Commenters generally supported the proposed measures to complement the DC function measure, particularly focusing on self-care/ADL measures. Commenters suggested that CMS consider using only one set of assessment items to measure function, as using a single set of function items would allow HHAs to focus on coding accuracy and avoid the confusion associated with multiple assessment categories.

The MSPB measure received mixed comments. Supporters of this measure believe that it provides information on the efficiency of home health providers and would help identify the costs associated with the delivery of high-quality nursing services. Comments that were critical of the measure stated that the measure's focus on spending rather than quality could create incentives to omit needed care services.

The falls with major injury measure received mixed comments. Some commenters noted that it is claims-based but noted that the measure includes only Medicare fee-for-service (FFS) patients. Others stated that falls are outside of a home health agency's control given that home health services are provided on an intermittent basis.

Some commenters offered suggestions for other possible measures to include in the expanded HHVBP Model, including advance care planning, access to palliative care services, timely and appropriate referral to hospice, interoperability, the average time between referral and initiation of care, follow-up care coordination, and meaningful measures for patients with chronic conditions that are not expected to improve.

Some commenters expressed concerns about burden and duplicative reporting with the QRP measures. One commenter suggested that CMS transition to using data sources that are not easily manipulated, such as claims data and patient experience responses instead of OASIS-based measures.

Response: We appreciate the comments that we received on the request for information. We are not responding to individual specific comments submitted in response to the RFI in this final rule, but these comments will be reviewed with stakeholders and the HHVBP TEP that provide input when considering changes to the HHVBP applicable measure set. Any changes to the applicable measure set will be made through future rulemaking.

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

In alignment with the President's Executive orders[88] 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.[89]

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

[88] 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."
[89] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.

metrics).[90] 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, will 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.[91] Previous studies have found that patients from underserved communities have higher rates of hospital readmissions, are more likely to be discharged without functional improvement,[92] 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

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[90] 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)

[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 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.

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.[93] 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.[94] Another study found that differences both within and across HHAs contribute to the overall disparities in patients' functional improvement.[95] 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.[96] 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.[97]

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 will its impact on underserved communities be?

● Feasibility: How long will it take to implement the approach? Are the necessary data currently being collected? How many HHAs will be included?

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[93] 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.

[94] 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.

[95] 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.

[96] 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.

[97] 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.

● 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 other 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 DES proportion and the LIS eligibility proportion is above 0.98. 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 will 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 regulatory text at § 413.338(a) will 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 will alter the effects of the HEA. We are also examining measures of the underserved population that are based on the percentage of patients with Medicaid as the only payment source.

F. Other Health Equity Measures

We are also exploring other health equity measures that will 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.

We received the following comments:

Comments: Commenters supported our efforts to advance health equity within the expanded HHVBP Model. Additionally, commenters provided specific comments, concerns, and requests related to the expanded HHVBP Model falling into the following themes:

While most commenters were supportive of efforts to incorporate health equity into the expanded HHVBP Model, some of the supportive comments also expressed concerns about implementation issues including provider burden of reporting requirements for equity measures. Some commenters expressly supported the adoption of the Health Equity Adjustment (HEA) used in the SNF VBP Program in the expanded HHVBP Model. Other commenters expressed concern that the expanded HHVBP Model may exacerbate HHAs' disincentives to treat some patients. One commenter suggested that we consider ways to incentivize agencies who care for underserved communities and/or chronically complex patients.

Response: We appreciate the comments that we received and are taking these comments into account, as appropriate, as we continue to work to develop policies, quality measures, and measurement strategies on health equity. We plan to review these comments with the HHVBP TEP to provide input to inform development of health equity quality measures.

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.[98] 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

[98] 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.

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 (Pub. L. 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 will improve access to home IVIG therapy for patients with PIDD. The Medicare IVIG Access Act mandated that Medicare 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.[99]

On September 28, 2017, Congress passed the Disaster Tax Relief and Airport and Airway

[99] 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.

Extension Act of 2017 (Pub. L. 115-63). Section 302 of Pub. L. 115-63 extended the Demonstration through December 31, 2020.

Division CC, section 104, of the Consolidated Appropriations Act, 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 (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 sets 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 subpart B. 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)[100] and IVIG Policy Article (A52509)[101]) provide direction on coding and coverage for the IVIG product at home. Through the Local Coverage Determination (LCD) for Intravenous Immune Globulin (L33610),[102] 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

[100] https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33610.
[101] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52509.
[102] Local Coverage Determination (LCD): IVIG (L33610) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33610&ContrId=389.

and regulatory requirements. Policy guidance for the LCD for IVIG[103] 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 27.

TABLE 27: 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 27 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 subregulatory guidance pursuant to the CAA, 2023 to reflect the expansion of the benefit to the items and services related to the home

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

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 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.[104] 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 will 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 will 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

[104] 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.

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.[105] 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, will 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

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

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),[106] 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 items and services benefit and the HIT services benefit 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 items and

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

services 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 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 durable medical equipment, prosthetics, orthotics, and supplies (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 final 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'".[107] 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. 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

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

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 will 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 will 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 will 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 the home health payment rate update percentage for such year. Therefore, in the CY 2025 HH PPS proposed rule, we proposed the 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).

Comment: We received a few comments on the CY 2025 update of the home IVIG items

and services payment rate. Overall, commenters remained supportive of CMS's implementation of the home IVIG items and services benefit, including the payment rate increase. However, one commenter stated that the LUPA-based rate calculation for the IVIG items and services payment rate undervalues the nursing and pharmacy services involved in the provision of home-administered IVIG. This commenter stated this rate does not account for costs such as travel time, dedicated one-on-one nursing, and other pharmacy-related expenses that happen remotely. A commenter also requested CMS publish an annual report on the home IVIG items and services benefit, similar to the HIT Monitoring Report.

Response: The comments regarding the methodology that established the initial home IVIG items and services rate are out of scope of this rule, as this policy was finalized in the CY 2024 HH PPS final rule; however, since the implementation of the home IVIG Demonstration Program, CMS has interpreted the services covered under this payment to be nursing services furnished in the patient's home. Indeed, the Medicare IVIG Access Act statutorily required this payment 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. In addition, section 1842(o)(8) of the Act states that payment may be based on the payment established pursuant to subsection (d) of section 101 of the Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012. We anticipate including a public monitoring report on the home IVIG items and services benefit on our Home Infusion Therapy (HIT)/IVIG webpage at https://www.cms.gov/medicare/payment/fee-for-service-providers/home-infusion-therapy once we have sufficient data.

After consideration of the public comments we received, we are finalizing the CY 2025 home IVIG items and services payment rate of $431.83 ($420.48 updated by the final home health payment update percentage of 2.7 percent ($420.48 * 1.027 = $431.83)). The final home IVIG items and services payment rate will be posted in the Billing and Rates section of the

CMS' Home Infusion Therapy (HIT) webpage (found at https://www.cms.gov/medicare/payment/fee-for-service-providers/home-infusion-therapy).

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's established methodology via the Home Health Prospective Payment System Rate Update Change Request or Technical Direction Letter (TDL) and posted on the CMS HIT/Home IVIG Services webpage.[108] 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).

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

VI. Home Health Agency Condition of Participation (CoP) Changes and Long Term Care (LTC) Facility Requirements for Acute Respiratory Illness Reporting

A. Home Health Agency 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. 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. 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.

As described in the CY 2025 HH PPS proposed rule, researchers have found that timely admission to home health, and in turn the initiation of services are key to good home health patient outcomes. To address concerns regarding the referral and acceptance process and their implications for prospective and current patients, we proposed 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 proposed, at § 484.105(i)(1)(i) through (iv), 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. These proposed elements were 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. We also proposed 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.

We received a total of 78 comments from individuals, health care professionals, national associations and patient advocacy groups. In the following section, we discuss the public comments received on § 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.

Comment: A few commenters supported the proposal for HHAs to develop, implement, and maintain an acceptance-to-service policy, with some observing that acceptance-to-service is an equity issue and that delays in finding appropriate care can worsen outcomes for patients. A commenter supported the clarification that HHAs should not accept patients they cannot serve. However, another commenter recommended that CMS ensure that the proposed acceptance-to-service policy does not result in the denial of access to services because the acceptance-to-service policy erroneously indicates that the HHA is unable to meet a specific patient's needs. A commenter stated that the acceptance-to-service policy would lead to improved workload distribution for HHA staff but expressed concern that HHA administrators may misrepresent the skills of the staff in order to accept more patients.

Conversely, other commenters expressed concern regarding the proposed policy, suggesting that the existing requirements already adequately address patient access to home health services and that HHAs would not accept patients to whom they could not reasonably expect to provide care. A commenter shared that HHAs may already use the proposed factors in determining whether to accept patients but that maintaining the information in an appropriate format would add burden. Commenters stated that the proposed CoP would not address the underlying challenges that prevent HHAs from accepting patients, such as staffing challenges, patient complexity, unnecessary work due to referrals being sent to multiple HHAs, care needs that are inappropriate for the home setting, an inability to identify a community practitioner to oversee patient care, and challenges in receiving responses to questions regarding care plans from referring providers. These commenters suggested not finalizing the proposed requirements and proposing different requirements in the future, with one commenter recommending that CMS convene a TEP to better understand the challenges associated with finding appropriate home health care.

Response: We appreciate the commenters support for these new proposals. While we agree that the existing CoPs already address some essential steps in the acceptance and admission process, we do not agree that these existing requirements fully meet the needs of patients. While we acknowledge the feedback highlighting the varying underlying challenges that may prevent HHAs from accepting patients, as noted by some commenters, delays in finding appropriate care can worsen outcomes for patients and acceptance-to-service may be an equity issue for patients with complex needs. The consistent application of an acceptance-to-service policy to all referrals, when combined with making certain information publicly available, is likely to reduce delays in finding appropriate care while ensuring that clinical factors are used to guide decision making on accepting patients to HHA service, so as to assure that an HHA is prepared to meet each patient's care needs.

We also agree with the commenter that the acceptance-to-service policy may lead to a better HHA staff workload distribution as HHAs use a more deliberative, equally applied approach in accepting patients for HHA services. In accordance with the requirements of § 484.105, the HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including providing optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs. As such, each HHA should already be well versed in understanding staff ability and skills, current workloads and other circumstances that may affect case load. These are well established concepts that we are formalizing within a policy that we expect will be applied equally and consistently when evaluating prospective referred patients. We appreciate the commenter sharing the observation that some HHAs have existing referral policies that reflect some of the requirements included in our proposal and that HHAs are already using these factors in determining whether to accept patients. We note that we also received a comment stating that one HHA accreditation organization already requires HHAs to have a referral policy. Therefore, we believe that many HHAs have existing policies and procedures that will support compliance

with these new requirements and minimize the aggregate initial effort necessary to work towards compliance.

Comment: A commenter stated that data collection and reporting for such a policy will create additional administrative burden for HHAs. Other commenters expressed general concerns about the potential burdens of developing and maintaining an acceptance-to-service policy, with one suggesting that CMS should reimburse HHAs for the time and effort required to develop and maintain such policies.

Response: We understand commenters concerns regarding burden, specifically, the development and maintenance of the policy. However, we believe the benefits to the referred and current patient, in terms of enabling more timely care and better outcomes outweigh the administrative costs of policy development. Furthermore, as noted previously, many commenters have acknowledged existing business practices that support compliance with the policy. We encourage HHAs to leverage their partnerships throughout the stakeholder community to gain exposure to existing practices that could assist in minimizing facility burden associated with compliance.

Comment: Some commenters suggested regarding ways to revise the proposed policy, such as addressing the HHA's ability to provide the required services, criteria to determine the patient's eligibility for care, and procedures for accepting referrals. A commenter also stated that appropriate patient placement with a home health agency is more nuanced than simply tracking staffing numbers and general competencies. The commenter recommended ensuring HHAs include nurse input to determine whether a patient placement within an agency is possible based on patient acuity and care levels.

Response: We agree that appropriate patient placement with a home health agency is complex and that it is important that the HHAs have the appropriate staff input to determine whether a patient placement within an agency is possible based on patient acuity, care levels, and HHA resources. We acknowledge that the skills and clinical knowledge of a nurse may be

beneficial to this process. However, we recognize that there are other clinicians, such as rehabilitation therapists, that may be appropriate as well. Therefore, we believe it is best to allow the HHA the flexibility to determine which staff members should be included in this process. We agree that HHAs should also consider including criteria to determine the patient's eligibility for care and procedures for accepting referrals as part of their acceptance-to-service policy to improve their referral acceptance process. While we agree that procedures for accepting patient referrals may fall within the scope of the CoPs, we do not believe that it is necessary to add this regulatory requirement for specific procedures at this time. We will continue to monitor the timeliness of patient access to HHA services and follow-on initial patient assessment activities to determine whether such regulations may be needed in the future.

Comment: A few commenters expressed concern that CMS did not discuss how HHAs would be evaluated for their compliance with the acceptance-to-service policy. Some of these commenters stated that HHAs would have to begin tracking patients that were referred to their agency but not accepted for service because currently HHAs only have data regarding patients to whom they provide care. In addition, commenters expressed concern that this policy would focus on access instead of quality and safety, and that surveyors would require training to be able to fairly and consistently evaluate compliance. A commenter recommended that CMS collect data regarding patients who are denied service, and that CMS provide oversight and enforcement to prevent HHAs from using capacity as a rationale for declining to provide service to patients with chronic or complex needs. The commenter stated that regulators could review referral and rejection lists, and that by analyzing these lists regulators can identify reasons for rejections and address those underlying reasons.

Response: The proposed and final policies focus on the health and safety of HHA patients by instituting regulatory policies that will reduce avoidable care delays that are known to increase the risk of hospital readmissions. We seek to ensure that eligible patients receive timely care to reduce the likelihood of these readmissions and other negative consequences that may

occur when a patient is referred for home health services but does not receive timely care. We expect each HHA to develop its acceptance-to-service policy taking into consideration the criteria outlined in the final CoP. HHAs will 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 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 should 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. HHAs will be assessed for their compliance with the requirements set forth at § 484.105(i). Section 484.105(i) does not include a requirement to track patients that are not accepted for service nor any other data collection requirements. HHAs are encouraged to track this information to ensure that their services align with the needs of the communities they serve. HHAs may use this data for their quality assessment and performance improvement (QAPI) programs to evaluate the services provided and examine potential areas of growth to best meet the needs of their potential patients. We remind HHAs that they are required to comply with Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, Title II of the Americans with Disabilities Act, the Age Discrimination Act of 1975, and section 1557 of the Affordable Care Act. Furthermore, interpretive guidance for the final policy will be released following the publication of this final rule and will provide additional information regarding oversight and enforcement of the requirements.

Comment: Some commenters shared that an acceptance-to-service policy for HHAs would inappropriately place the entire responsibility for timely initiation of care on HHAs when this responsibility is shared between referral sources and HHAs. The commenter also stated that there are often communications gaps between patients, referral sources, and HHAs which can lead to wasted time and resources (for example, a patient being referred to two HHAs or an HHA which is not notified when the patient is no longer at home and has been admitted or readmitted for inpatient care).

Response: We agree that HHAs are responsible for their own policies and procedures and share patient care responsibilities with the practitioners that oversee the HHA plan of care. The acceptance-to-service policy includes four minimum requirements related to clinical factors that influence whether an HHA should accept or decline a referral to ensure the health and safety or the referred patient by matching HHA services to patient needs. Within this structure HHAs may tailor their policy to address additional concerns and procedural delays and challenges that they typically face in the referral and acceptance process. It is the responsibility of the HHA to work with its referral sources by educating them on the HHA acceptance-to-service policy and services the HHA offers with the goal to minimize the communication gaps.

Comment: A commenter supported the statement that acceptance-to-service should not be based on payment source; conversely, a few other commenters did not support this concept. A commenter expressed that because HHAs lose money providing care for some patients they must have a patient load balanced across payers with higher and lower payment rates. This commenter also expressed that while an HHA may be a Medicare-certified provider, they may not be in-network for all MA plans, and even those for which they are in network may have lengthy and complicated prior authorization processes. This commenter also expressed concern that the proposal was intended to improve access for patients with Medicaid and stated that this is an inappropriate use of the Medicare CoPs.

Response: In accordance with § 484.105, an HHA must organize, manage, and administer its resources to provide optimal care to achieve the goals established in each patient's individualized plan of care. When accepting patients, the primary consideration of all HHAs must be whether the HHA has the resources available to meet the needs of the prospective patient, so as to avoid accepting those patients for whom the HHA does not have a reasonable expectation of being able to meet the patient's needs in their home environment.

Comment: A commenter stated that it is not uncommon for an HHA to accept a patient for whom they cannot provide sufficient care and that the patient's needs may be met by non-profits.

Response: 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 the prospective patient is or is not appropriate for the HHA to accept for service. At § 484.60, we require HHAs to accept patients for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in their place of residence. Therefore, the information the commenter shared reflects a lack of compliance with current regulations. Patients and caregivers may choose to use additional community services to augment the services provided by an HHA, but an HHA may not choose to provide reduced services for the convenience of the HHA when the patient's need for a higher level of services remains unchanged. In accordance with § 484.60, HHAs are responsible for implementing an individualized plan of care that specifies the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, and that identifies patient-specific measurable outcomes and goals identified by the HHA.

Comment: A commenter stated that the proposed rule did not provide a clear definition of "timely initiation" which would be important in evaluating acceptance-to-service. This

commenter stated that the current definition of "timely initiation of care" is part of the HH QRP based on OASIS data.

Response: We agree that this term may be used and defined in other HHA programs that are not part of the CoPs. The specific proposed requirement at § 484.105(i) did not include the term “timely initiation” and it would not be appropriate to define in the CoPs a term that was not used in the CoPs.

Final Rule Action: After consideration of public comments, we are finalizing the acceptance-to-service policy at § 484.105(i)(1) as proposed.

3. Updates to the Home Health CoPs to Require HHAs to Make Information Public on Offered Services and Service Limitations (§ 484.105(i)(2))

Home health agencies have the ability to select the services that they furnish and the geographic areas that they serve. Knowing which areas are served by an HHA and which services an HHA does and does not provide will assist referral sources, patients, and caregivers engaged in a search for home health services in identifying the most suitable HHA. Likewise, each HHA has fluctuating staffing levels and staffing competencies affecting its capacity to deliver patient care and provide its typically offered services. Therefore, at § 484.105(i)(2) we proposed to require that HHAs make public accurate information regarding the services offered by the HHA, such limitations on specialty services, service duration, and service frequency to further inform the search efforts of all referral sources. We also proposed that HHAs review this information at least annually. This will facilitate the search for an HHA to meet a patient’s needs, both from clinical referral sources, and from patients and caregivers directly seeking care. The goal is to reduce the delay between the time when a patient is identified as an eligible candidate for home health care and the time when care is initiated 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 adverse outcomes, including 30-day rehospitalizations.

In the following section we discuss the public comments received and our responses on proposed § 484.105(i)(2) which would require HHAs to make public accurate information regarding services offered, service limitations, and service frequency.

Comment: A few commenters expressed support with recommendations for the proposed requirement for HHAs to make public accurate, current information on the services they offer. These commenters stated that this could expedite connecting beneficiaries to agencies and provide meaningful data about which agencies accept patients with complex and long-term needs. A commenter stated that the proposed requirement will provide useful information about areas where there may be gaps in HHAs that provide specific services or are able to accept complex patients. Likewise, a commenter noted that the proposed regulation promotes public transparency and highlights the importance of timely initiation of care. A commenter recommended that the information be presented in a manner that is user-friendly, and culturally and linguistically appropriate. Another commenter recommended additional information that would be useful for patients in selecting an HHA, including languages in which staff are fluent, a count of staff fluent in each language, and patient to staff ratios.

Response: We thank commenters for their support and for highlighting how this policy will help promote transparency, ensure timely patient admission, and thus initiation of HHA services. We agree with the commenters that making available information about the services offered by the HHA and any limitations on those services may provide public transparency and highlights the importance of timely initiation of care as well as provide useful information about areas where there may be gaps in HHAs that provide specific services. We acknowledge the importance of providing information in an accessible manner. We are providing HHAs with the flexibility to provide information regarding their services in multiple formats (for example, Care Compare). We remind HHAs of their requirement to comply with section 508 of the Rehabilitation Act when developing and publishing this information for the public.

Comment: Several commenters stated that they did not support the proposed adoption of an acceptance-to-service policy requirement because of concerns that the data could not reasonably be kept up to date and would therefore not be able to meaningfully help patients and referrers identify appropriate HHAs for care needs. Several commenters stated that staffing and ability to accept new referrals changes on a daily basis and that changing publicly reported information that frequently could be confusing for patients and other providers. Other commenters recommended that CMS establish standards for updating publicly posted information more frequently than the proposed annual review of information. These commenters stated that staffing levels change regularly and suggested timeframes for updates such as monthly or upon a major change in service abilities. For example, a few commenters stated that the requirement to update public information about acceptance-to-service policies on an "annual or as necessary" basis is not sufficiently clear. These commenters recommend that CMS provide more detail on what would qualify for the "as necessary" standard. Other commenters sought additional clarity on how frequently this information should be updated and how the information would be evaluated.

Response: We believe that these comments are not related to the acceptance-to-service policy set forth on proposed §484.105(i)(1), but to the proposed requirement at § 484.105(i)(2) that HHAs would make publicly available information regarding the services they offered, and any limitations related to types of specialty services, service duration, or service frequency. We thank commenters for clarifying how frequently HHA services are updated or changed. While we acknowledge the potential challenges of keeping this information up to date, failing to do so may contribute to delays in patients receiving needed home healthcare that may increase the likelihood of rehospitalization, as well as increase the number of dual eligible patients and other vulnerable populations at risk for poor outcomes. According to one study published in 2021, when the initiation of home health services is significantly delayed (that is, from 8 to 14 days after discharge), the odds of rehospitalization for diabetic patients were four times greater

compared to patients receiving home health service initiation within 2 days.[109] Yet the rate of timely initiation of home health care varies significantly, indicating that the referral and acceptance process is in need of improvement.

While making this required information publicly available may initially present a new challenge for HHAs, the greater clarity between HHAs, patients and referral sources may improve the HHAs relationships with the community they serve and reduce instances of avoidable confusion and delays. To ensure that the information presented to the public is accurate, we are revising the policy to require HHAs to review publicly facing information as frequently as services are changed, but no less often than annually. We would expect HHAs to update the information regarding their services provided and service limitations if the HHA anticipates it will not have a service available for 3 to 6 months. Changing a service means the HHA has formally altered the services it offers, whether by adding, discontinuing, or temporarily pausing or restricting a service. For example, a change in service may include an employee taking an extended leave of absence (that is, care for a family member, recovery from a serious illness or procedure, maternity leave) or the addition of a new contract employee that provides speech language pathology services, which a HHA may not have provided before.

Providing the most up to date information on services provided and service limitations will allow patients, their families, and/or their caregiver(s) to make educated decisions about which HHA will best meet their physical, psychosocial, and rehabilitative needs. HHAs are already required by § 484.105 to document, in writing, the services that they furnish. The governing body is responsible for assuring that this is done as part of their oversight responsibilities set forth in § 484.105(a). As such, we would expect to see evidence of governing body decision making on the services offered, corresponding revisions to the written list, and corresponding updates to its public facing information. After publication of this final rule, CMS

[109] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8197411/.

will provide additional guidance on enforcement through memoranda and updates to the State Operations Manual (Pub. 100-07), as needed.

Comment: A commenter expressed concern that the policy may prohibit HHAs from accepting patients that they would be able to serve given their actual staffing, but that their published acceptance-to-service policy would indicate that they could not serve.

Response: The information about services and limitations made publicly available would in no way prohibit an HHA from accepting a referral. Referral acceptance is governed by the HHAs acceptance-to-service policy set forth in §484.105(i)(1), which requires HHAs to develop and implement a policy based on specified clinical factors to ensure that HHAs only accept those patients for whom they have a reasonable expectation of being able to meet the patient's care needs in their home environment.

Comment: A commenter stated that providing information regarding an HHA's capacity on a public website would not provide meaningful information to patients because home health referrals must be completed by a medical professional and therefore patients and their families would not be able to self-refer to such a provider.

Response: We did not propose, nor are we finalizing, a requirement for HHAs to post information regarding their capacity on a website. Rather, we proposed and are finalizing a requirement that HHAs make publicly available information regarding the services that they offer and limitations on those services, such as offering nursing services but not advanced wound care services as a specialty. The capacity of an HHA to deliver care to a referred patient is accounted for in the internal policy that HHAs will develop and use when making acceptance-to-service decisions. By accounting for the referred patient's anticipated needs and considering the HHA's available resources, HHAs will self-assess their capacity to serve the referred person and ensure their health and safety.

We do not agree with the suggestion that patients and families are not involved in identifying available HHA care. While the official home health referral is completed by a

medical professional, many patients and their family members face the task of seeking out home health care to facilitate the official referral process. If a patient's practitioner decides they need home health care, the patient has the right to participate in choosing the home health agency to meet their care needs. While patients have choice, those choices may be limited based on the services offered by HHAs, limitations on those services, insurance type, and other factors.[110] Patients and caregivers have recounted conducting their own searches for care, often with great difficulty. This population has unique needs and circumstances needs that may make finding the right HHA challenging, and they may not have access to information needed to target their search for an HHA in an effective and efficient manner. Patients from community-based referral sources tend to be Medicaid recipients, have cognitive impairments, and are more socially vulnerable 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.[111] Encouraging patients and their family members and/or caregiver(s) to be more active participants in decision making improves patient outcomes.[112]

Comment: Several commenters did not support a requirement to publicly post information regarding a HHA's acceptance-to-service policies because many HHAs already post these data on their websites. Some commenters also stated that information about services provided is available on the CMS Care Compare website and recommended this as the appropriate location for information about agency services. A commenter recommended linking HHA websites to their information on the Home Health Compare website to improve the ease of finding additional information about these organizations. A commenter stated that CMS posts similar information regarding hospice providers and stated that CMS can track and post these data for HH providers as well.

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[110] https://www.cms.gov › HHQIHHBenefits.
[111] Social Vulnerability and Medical Complexity Among Medicare Beneficiaries Receiving Home Health Without Prior Hospitalization, Julia G. Burgdorf, PhD, Tracy M. Mroz, OTR/L, PhD, and Jennifer L. Wolff, PhD. Innovation in Aging, 2020, Vol. 4, No. 6, 1–9 doi:10.1093/geroni/igaa049.
[112] https://www.ahrq.gov/health-literacy/professional-training/shared-decision/tool/resource-9.html.

Response: To clarify, we are not requiring HHAs to publicly post information regarding an HHAs acceptance-to-service policy. The acceptance-to-service policy is for an agency's internal use and is intended to compliment any current policies and procedures HHAs may use for tracking referrals and assessing the suitability of the referral relative to the HHA's capacity. Instead, HHAs will be required to publicly post information regarding their services offered and the limitations of these services. CMS recognizes that some of the information about services offered may be available on Care Compare. Care Compare is designed to be an easy-to-access, convenient source of information about provider quality.[113] HHAs may use Care Compare to facilitate compliance with this requirement.

Alternatively, providing information regarding an HHA's service through its website may also facilitate compliance with this requirement. HHAs thus have flexibility in achieving compliance with this requirement to ensure that public facing information regarding services offered by an HHA are available. As previously discussed, we remind HHAs of their requirement to comply with section 508 of the Rehabilitation Act to ensure that publicly facing information is accessible.

Comment: A commenter stated that publicly posting information regarding services offered will have minimal benefit because this information will not address individual patient specific circumstances and therefore may still not provide patients information regarding whether the HHA would be able to address their needs.

Response: The posting of the services provided by an HHA, and any service limitations aims to increase transparency and allow patients and their caregiver(s) to make informed decisions when selecting an HHA, including the ability to speed their search by eliminating those HHAs that do not offer the services the patient needs or whose limitations on services make the HHA an unsuitable match. This allows patients and their family members and/ or caregiver(s) to have a better understanding of what HHA may best fulfill their needs and efficiently focus their

[113] https://www.cms.gov/medicare/quality/home-health/home-health-star-ratings.

efforts to achieve a timely admission and initiation of HHA care, thus benefitting the patient's health and safety.

Comment: A commenter recommended that instead of publishing information regarding services provided and capacity, HHAs should be required to disclose any known delays to the services ordered on referral prior to admission.

Response: We are not requiring HHAs to publish information regarding capacity, however, this policy does not prevent HHAs from doing so. Section 484.105(i)(1) requires the HHA address criteria related to their capacity, which includes anticipated needs of the referred prospective patient, case load and case mix, staffing levels of the HHA, and skills and competencies of the HHA staff. Requiring HHAs to publish this information may be too burdensome, as these variables may change often. We are requiring HHAs to share information with the public regarding limitations related to specialty services, service duration, or service frequency. In accordance with § 484.60, we would expect HHAs to only accept patients that they are able to meet the medical, rehabilitative, nursing, and social needs of. Additionally, § 484.60(a)(2)(iv) requires the individualized plan of care to include the frequency and duration of visits to be made. As previously discussed, § 484.55(a)(1) requires the initial assessment visit to be held within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician or allowed practitioner-ordered start of care date.

Final Rule Action: After consideration of public comments, we are finalizing the acceptance-to-service policy with revisions. Specifically, we are updating the frequency with which HHAs must review the publicly facing information regarding their services provided and any service limitations to ensure this information is up to date and accurate. Specifically, we are revising § 484.105(i)(2), to require HHAs to review the publicly facing information as frequently as services are changed, but no less often than annually.

4. Request for Public Comments

In the proposed rule we requested additional feedback of topic areas related to the acceptance-to-service policy. Specifically, we requested 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 requested public comment regarding other ways to improve the referral process for referral sources, patients, and HHAs. Many of the commenter's suggestions overlapped with the comments received for the proposed acceptance-to-service policy and the RFI on "Plan of Care Development and Scope of Services." We categorized the comments into key themes, as follows: alternative ways to address delays, improved referral process, and overall plan of care development/scope of service. A few commenters suggested CMS focus on improving the establishment of the plan of care as part of the referral process. While other commenters suggested CMS engage clinicians to gain greater insight on what is happening in the field and using claims-based measures to gather data, educating hospital discharge planners to improve pre-discharge communications with patients and caregivers, and evaluating the impact of PDGM on HHAs. We appreciate to wide variety of comments received on the question and may use this feedback to inform additional rulemaking.

5. Out of Scope

Comment: Some commenters recommended increasing the focus on supporting HHAs by requiring that all payer processes for recoupments, vendor holds, undisclosed rate decreases and claim payment denials be made transparent by payer sources who frequently disrupt the financial operations of HHAs.

Response: The CoPs do not regulate payer processes; therefore, this suggestion is out of scope for the CoPs.

Comment: A few commenters recommended reinforcing the importance of timely initiation of service by adopting an initiation of care measures in the HHVBP program.

Response: The HHVBP is not within the scope of the HHA CoPs; therefore, we are not accepting this suggestion.

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 facility 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 Act, we proposed to establish the ongoing collection of a set of data elements necessary to quickly identify threats to resident health and safety and initiate requisite responses.

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 (IFCs) 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 facility residents. The data highlighted how LTC facilities played a large role in viral transmission and that LTC facility 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 facility 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 facility 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 62440, 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 specified a lesser frequency) and modified the specific data elements to be reported. The November 2021 final rule stated that until December 31, 2024, facilities would be required to report electronically, 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 (86 FR 62421).

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).[114] This June 2023 final rule 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[115]), 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.[116,117] 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.[118] 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.[119] 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

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[114] June 2023 Final Rule. https://www.govinfo.gov/content/pkg/FR-2023-06-05/pdf/2023-11449.pdf
[115] 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.
[116] 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.
[117] 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/.
[118] 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.
[119] Vital and Health Statistics, Series 3, Number 47 (cdc.gov) (https://www.cdc.gov/nchs/data/series/sr_03/sr03-047.pdf).

respiratory viruses in this setting.[120] 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.[121]

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.[122] 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. The resources made available during the PHE response helped

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[120] Morbidity and Mortality Weekly Report (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).
[121] 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/).
[122] Vital and Health Statistics, Series 3, Number 47 (cdc.gov) (https://www.cdc.gov/nchs/data/series/sr_03/sr03-047.pdf).

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. 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.

In the proposed rule, we provided a detailed discussion regarding the data produced by the respiratory illness reporting requirements for LTC facilities and how the insight provided by the data collected positively impacted resident health and safety by guiding actions to reduce the prevalence of respiratory illnesses through enhanced planning, technical assistance, resource allocation, and coordination at the facility, local, State, and Federal levels. We encourage readers to refer to the proposed rule for this detailed discussion (89 FR 55404-55406).

3. Provisions of the Proposed Regulations and Analysis and Response to Public Comments

In response to the proposed rule, we received 73 total comments from industry commenters, such as national associations, leadership, and facility staff. We received very few comments from advocacy organizations and no comments from anyone identifying themselves as residents or family advocates. In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received, and our responses to them, and an explanation for changes in the policies we are finalizing.

a. 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 considered 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,[123] adults 65 years and older represented more than half of COVID-19 hospitalizations during October 2023 to December 2023.[124] 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.[125] 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.[126]

The elevated risks of respiratory viruses in the post-PHE era present ongoing threats, both direct and indirect, to resident health and safety. As such, we proposed to continue some of the reporting requirements finalized in November 2021 and set to expire in December 2024. Specifically, we proposed 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 proposed 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, we proposed to require facilities to electronically report information about COVID-19, influenza, and RSV in a standardized format and frequency specified by the Secretary. We proposed to continue weekly reporting through the CDC's NHSN. To the extent to be determined by the Secretary, through this

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[123] https://covid.cdc.gov/covid-data-tracker/#trends_weeklyhospitaladmissions_select_00.
[124] CDC COVID Data Tracker: Hospital Admissions (https://covid.cdc.gov/covid-data-tracker/#datatracker-home).
[125] 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.
[126] Respiratory Disease Season Outlook (cdc.gov) (https://www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html).

rulemaking cycle, we proposed 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).

Comment: A few commenters expressed support for our proposal to extend the requirements for respiratory illness reporting in LTC facilities. These commenters stated that sustained data collection and reporting provides valuable information for guiding infection control interventions; keeping LTC facility residents, family members, and staff safe; and directing resources where they are most needed. A commenter specifically expressed support for including other respiratory illnesses in the required NHSN reporting. A commenter stated that understanding health related social needs and demographic information may be helpful in addressing health inequities.

Response: We thank commenters for their support of LTC facility acute respiratory illness data reporting to NHSN. The Infection Control requirements at §483.80 are a comprehensive set of requirements that include an infection prevention and control plan (IPCP) based upon the facility assessment as set forth in §483.71. Consistent data on COVID-19, influenza, and RSV is essential for infection control efforts to protect the health and safety of residents as well as facility staff. We acknowledge that every LTC facility is different, with different resident populations, varying types of acuity and medical needs, and resource challenges. As such, our goal to minimize the risk of severe illness, hospitalization and death

from respiratory viruses is supported by situational awareness that occurs with data that can be analyzed on a regular frequency, easily available and acted upon.

Comment: A commenter recommended requirements that LTC facilities include at least one full-time dedicated infection preventionist (IP) to support reporting and a robust IPCP.

Response: We appreciate the recommendation that LTC facilities use at least one full-time dedicated IP. Existing provisions at §483.80(b) require facilities to have an IP work at least part-time at the facility. Additionally, if the facility assessment identifies the need for additional resources above the minimum requirement of a part time IP position, then the facility should staff to the appropriate level to care for its resident population. We believe that these existing requirements set forth a feasible and achievable minimum health and safety standard that supports infection prevention and control, while also considering the differences and varying needs of all of the LTC facilities that must comply with these minimum health and safety requirements.

Comment: Another commenter supported required respiratory illness data reporting and recommended establishing policies to ensure that resident privacy is protected.

Response: We appreciate the commenter's support for acute respiratory illness data reporting as well as the recommendation to ensure that residents' privacy is protected. Existing provisions at §483.10(h), "Privacy and Confidentiality," require LTC facilities to ensure and respect a resident's right to personal privacy and the confidentiality of their personal and medical records. This includes but is not limited to using appropriate administrative, physical and technical safeguards to ensure confidentiality, integrity and security of personal and medical records. Regular training for LTC facility staff on privacy and security best practices is essential. Also, §483.10(g), "Resident rights", requires LTC facilities to respect a resident's right to privacy in communications. This includes mail, letters, packages and other materials. The LTC facility must also ensure that residents' have reasonable access and privacy in electronic communications, including email, video communications and internet access for research.

Hence, we believe the LTC facility is already required and should have policies to ensure resident privacy of their medical records, including respiratory illness reporting based on these existing requirements.

Comment: Many commenters recommended that CMS revise the frequency of NHSN reporting to monthly or quarterly or, in some cases, annually to reduce the administrative burden associated with the proposed requirement. A few commenters stated that weekly reporting is a pandemic level frequency for reporting and stated that this is no longer appropriate. Other commenters suggested reporting during peak respiratory virus season (that is, fall and winter). A few commenters suggested that facilities report to NHSN only in the event of an outbreak. A few commenters recommended allowing reporting of snapshot data for the week instead of cumulative data.

Response: We thank the commenters for their feedback. Elevated risks of respiratory viruses in the post-PHE era present ongoing threats and there will be more burdensome respiratory virus seasons and periodic surges for the foreseeable future that threaten the health and safety of LTC facility residents.[127] In response, 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.[128] Likewise, we believe it is vital to maintain national surveillance of these emerging and evolving respiratory illnesses as a means of guiding infection control interventions to keep residents safe. To achieve this the most useful data are those that are timely and actionable. It is in the best interests of LTC facility residents to protect them by continuing year-round surveillance to monitor for respiratory viruses. Such

[127] Respiratory Disease Season Outlook (cdc.gov) (https://www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html).
[128] 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 https://www.cdc.gov/respiratory-viruses/whats-new/track-hospital-capacity.html.

surveillance will provide actionable data for LTC facilities, healthcare quality improvement organizations, and public health agencies.

The proposed requirements are scaled back and streamlined in comparison to the current post COVID-19 PHE requirements. As such, the CDC has combined the respiratory illness reporting fields in NHSN and created one simplified reporting form (a reduction from four forms) to support the data collection. For additional context, this streamlined data collection will eliminate over 30 data fields that LTC facilities will need to address in the NHSN system. Continuing the collection of the minimal necessary data for weekly data reporting to NHSN will maintain a level of situational awareness that will protect resident health and safety, while reducing reporting burden on LTC facilities. Weekly reporting allows for public reporting in real time and on a regularly occurring basis. This ensures that a variety of entities across the local, State, and Federal levels (such as, LTC facilities and associations, CDC, Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs), state and local health departments) can monitor data with a minimal data lag and allow for quicker, direct response efforts to outbreaks among LTC facility residents.

Furthermore, we are not collecting only a "snapshot" of data, as suggested, because the required data to be reported has been streamlined to represent the minimum necessary data and there is a need to keep the collection period consistent (Monday through Sunday) to ensure the reliability of the data. Facilities will submit data through the NHSN reporting system once per week, representing cumulative vaccination coverage, new positive tests, and new hospitalizations that occurred during the week of reporting. Therefore, we believe that a weekly reporting frequency at this time is appropriate. However, we note that the requirements we are finalizing allow the Secretary the discretion to revise the frequency of reporting, and we will continue to monitor the utility of the reporting requirements and changing needs for the data collection.

Comment: Many commenters recommended not finalizing proposals related to continued reporting of respiratory viruses through the NHSN and recommended that CMS allow the

existing requirements for NHSN reporting to end on December 31, 2024, as currently provided for at §483.80(g). Commenters indicated that the continuation of data collection would divert resources from providing direct patient care and other important initiatives, such as quality improvement. Many commenters stated that the proposed reporting requirements are too time consuming and therefore would create administrative burden on LTC facilities that may outweigh the benefits of data reporting. Commenters were concerned that this reporting is resource intensive and would require LTC facilities to increase staffing levels to comply with all the steps of data collection, verification, and submission (including addressing a changing population of staff and residents) and stated that increasing staffing would be difficult because LTC facilities are currently facing staffing challenges. Some commenters specifically highlighted the potential burden on small facilities with minimal staff. A few commenters stated that data collection within the NHSN will not lead to improved care for residents and that the benefits of reporting that were seen during the PHE (including PPE allocations, strike teams, and test kit allocations) are no longer associated with NHSN reporting.

Response: We appreciate the feedback from these commenters; however, timely data reported on acute respiratory illnesses is essential to help guide targeted efforts to reduce severe illnesses and deaths among the resident population. A data driven approach will guide infection prevention and control interventions and LTC facility operations that directly relate to resident health and safety. As discussed previously, we want to emphasize that the requirements we are finalizing are scaled back and streamlined in comparison to the current post COVID-19 PHE requirements. For context, the streamlined data collection will reduce the number of NHSN forms from 4 to 1 and eliminate over 30 data fields that LTC facilities will need to address in the system. Therefore, we are finalizing the proposed policy, which will continue the collection of the minimal necessary data needed to maintain a level of situational awareness that we believe will protect resident health and safety in LTC facilities across the country, while reducing reporting burden on those facilities.

Comment: Many commenters stated that the proposed reporting requirements would require LTC facilities to report duplicative data through the CDC's NHSN. Commenters stated that relevant COVID-19 reporting has been incorporated into other systems and programs, and other respiratory illnesses are collected through the Minimum Data Set (MDS). Commenters also mentioned that infection data are already reported through other mandatory mechanisms such as reporting surveillance data to local authorities, public health agencies or departments of health as part of infection control requirements, including clusters of respiratory virus symptoms and information about confirmed cases. Commenters stated that because of these other data collection channels, requiring continued reporting through the NHSN would be unnecessary and duplicative, and recommended that CMS and CDC coordinate with public health agencies to access the data. A few commenters also noted that NHSN has separate guidelines for reporting data which are different from the guidelines for reporting the same data via the Minimum Data Set (MDS), which increases administrative reporting burden. A few commenters stated that data submission through MDS is preferable because these data can be linked to resident-specific demographic and socioeconomic data and can be used to inform care plans. Some commenters recommended only requiring LTC facilities to report on items not reported via MDS. A commenter recommended reporting the data through a system similar to Internet Quality Improvement and Evaluation System (iQIES) that would automatically pull the data. Lastly, a few commenters also noted that with the release of updated public health guidance in March 2024, CDC began shifting to a more standardized approach toward reporting on the incidence of respiratory viruses and recommended that CMS align nursing home requirements with this guidance. A commenter recommended that CMS convene a task force to study what high value data should continue to be collected from LTC facilities and consider adding to existing reporting platforms.

Response: We acknowledge that differing mechanisms for reporting some of the proposed respiratory data elements exist beyond NHSN, such as reporting through MDS.

However, while there is some overlap between NHSN and MDS collections, specifically resident vaccination data, streamlined data regarding acute respiratory illnesses including COVID-19, influenza, and RSV, as we proposed, are not currently captured in MDS. CMS and the CDC are committed to collecting the minimum data fields necessary to inform public health response and protect LTC facility residents. NHSN reporting provides useful data that are timely and actionable in real time on a routine cadence (weekly), unlike the MDS, which is collected at longer intervals that are dictated by reporting requirements unrelated to acute respiratory illnesses. An MDS must be completed for each resident upon admission, and then at regular intervals, typically every 3 months, or whenever there is a significant change in the resident's condition (see §483.20, "Resident assessment"). The timing of MDS data collection and reporting does not support facility-level acute respiratory illness situational awareness, since minimal data lag is needed to inform response efforts. Technical assistance and resource allocation may be delayed or omitted due to reduced or dated available information.

We also acknowledge that varying State health departments may also have reporting requirements for respiratory illness data. However, we believe that there is value in collecting this information at the Federal level. The NHSN data reports are accessed by State health departments to provide actionable data. The CDC 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, publicly available national vaccination data are critical for decision making, targeting outreach for vaccination campaigns efforts, insights into vaccination disparities and for vaccine effectiveness studies.[129] NHSN data was used by the CDC and QIOs to contact facilities with high vaccination coverage in order to

[129] 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.

understand the successful strategies they employed and promote these strategies to other LTC facilities via webinars. Moreover, 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 LTC facilities educate their staff, residents, and families to remove barriers to vaccination.

As noted previously, with this final rule we have streamlined data reporting to reduce burden, subsequently the CDC reduced reporting burden by creating a simplified and more efficient reporting form. Respiratory illness reporting fields for COVID-19, influenza and RSV are combined into a single data entry form (previously there were four), providing a significantly simplified and improved user experience. The CDC has invested in enhanced user support, an improved helpdesk ticket response system and training tailored to the LTC community to support the use of NHSN. In addition, there are some projects underway with LTC industry stakeholders to modernize data collection as well as improving interoperability with State Immunization Information Systems.

Comment: A few commenters did not support continued respiratory virus reporting through the NHSN because of technical challenges with the NHSN. Several commenters noted that the NHSN system experiences regular technical issues and lags in service that would be made worse by the continued and additional reporting by facilities. These commenters stated that the NHSN is slow and there are lengthy delays even for small amounts of data. These commenters also expressed concern that the NHSN help desk has long wait times and that the process for staff to gain initial access to the system is lengthy. Some commenters stated that there are frequent technical issues with NHSN which could lead facilities to be non-compliant in data reporting through no fault of their own. A few commenters expressed concerns about privacy and sharing sensitive information that could be at risk due to issues such as data breaches and unauthorized access. A commenter stated that by adopting these requirements through the

CoPs, CMS creates a risk that facilities may become non-compliant with the CoPs due to NHSN technical issues.

Response: We appreciate the comments regarding technical challenges with the NHSN. Through its data modernization efforts, CDC continues to work to strengthen the support available to the LTC community. The CDC publishes regularly scheduled updates and associated trainings, for which they notify the LTC community by email blasts and newsletters. Training webinars are available for replay and can be accessed in the NHSN section of the CDC website.[130] We understand the commenters' concerns about technical challenges regarding the reporting of the required information. These concerns about noncompliance due to NHSN technical issues could be mitigated with documentation of technical issues and the facility's communication with CDC to get issues corrected. CMS does not expect LTC facilities to be penalized for limitations to compliance that are outside of their control, and this has not been the approach taken by CMS regarding enforcement of the PHE COVID-19 reporting requirements or the current post-PHE reporting requirements.

However, existing requirements at §483.10(h)(3) set out the facility's obligation to protect each resident's right to secure and confidential personal and medical records. CMS expects all LTC facilities to protect resident data and information. Data breaches and unauthorized access are important concerns that the facility can mitigate by establishing clear and strict data security policies; limiting physical and electronic access to resident data, regular training on privacy and sharing sensitive information; and using encryption and secure communication protocols. If a data breach or unauthorized access occurs that was or should have been within the LTC facility's control, CMS would evaluate the circumstances for the performance of that individual LTC facility. For example, if a LTC facility allowed access to resident medical records to personnel that had no legitimate reason for access to those records and unauthorized access occurred, CMS might cite the LTC facility. Data breaches can impact

[130] https://www.cdc.gov/nhsn/ltc/index.html.

any entity, even the Federal Government, and we expect that LTC facilities will take the appropriate actions to correct and limit any damage or injury to residents from any data breach or unauthorized access to their medical or other personal information.

Comment: Several commenters recommended that HHS invest in the infrastructure needed to make the voluntary sharing of important data on infectious diseases less burdensome. Some of these commenters stated that this would be particularly important for the PAC setting because of the relative lack of interoperable electronic health records (EHRs) across these facilities. A few of these commenters expressed concerns that establishing requirements for participation for respiratory illness data reporting may threaten Medicare participation, facility financial viability, and access to care. Several commenters suggested that CMS should work with state government, local health departments and the provider community to determine how best to share data across entities and what data elements are most valuable in responding to PHEs, thereby reducing redundancy and administrative burden. Many commenters recommended that CMS collaborate with state health agencies to access surveillance data reported by facilities to mitigate the need to report to multiple agencies. A few commenters suggested that NHSN be directed to obtain data from state agencies to reduce duplication of effort. Commenters also stated that reporting requirements vary across agencies and recommended aligning these requirements. A commenter specifically recommended using OSHA's upcoming Infection Disease Standard to standardize data collection for healthcare professionals, a group that the commenter stated was omitted from the proposed reporting requirement.

Response: We thank commenters for their feedback on ways to make reporting less burdensome. The current lack of interoperability of electronic health records (EHRs) in the PAC setting makes it even more important to use the NHSN since it is set up to accept data that is collected, verified and submitted by all the LTC facilities across the country, whether they have an EHR system or not. We appreciate the support for transitioning to, and using, more modern, flexible approaches and networks that support data exchange between and across public health

and healthcare institutions to modernize the public health information infrastructure. We also appreciate the suggestion that NHSN should obtain data from State agencies to reduce provider burden, however this suggestion is not viable for many reasons, including the lack of consistent definitions of data elements across States, the fact that all States do not require data submission of all data elements that are being finalized, and that States systems may not be set up to send data to NHSN in the manner that is most valuable for situational awareness.

Regarding the omission of data collection for healthcare personnel, we note that we considered the utility of LTC facility respiratory illness data to monitor and protect residents against respiratory illnesses and the ongoing need for such data given the diverse respiratory disease threats. Currently, LTC facilities only report on staff vaccination status quarterly and we did not believe there was enough of a use case to support continued mandatory reporting of staff data. However, we note that at §483.80(g)(2)(i) we proposed that LTC facilities would need to report on relevant confirmed infections for staff in the event of a PHE. Furthermore, staff vaccination status is currently reported through the SNF Quality Reporting Program (QRP) under the SNF QRP measure "COVID-19 Vaccination Coverage among Healthcare Personnel".

Comment: Several commenters asserted that they did not support continued reporting requirements because LTC facilities are the only healthcare setting that is still being required to report this data. Some of these commenters expressed that by only requiring this data for one narrow sample of the population (that is, residents of LTC facilities) CMS would not be able to track infections across the overall population.

Response: We thank commenters for their feedback, however, we note that the assertion is incorrect. CMS finalized proposals for hospitals and CAHs to continue ongoing (that is outside of a PHE) reporting on data related to influenza, COVID-19, and RSV to NHSN. In addition, we finalized proposals for hospital and CAHs to report on additional data categories that could be required during the event of a declared PHE. These proposals were finalized on August 28, 2024, as part of the final rule titled "Medicare and Medicaid Programs and the Children's Health

Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes" (89 FR 69913).[131] The requirements for hospitals and CAHs will be effective on November 1, 2024, and we refer readers to the final rule for more detail.

Comment: A few commenters recommended that CMS align the decision on more detailed demographic data reporting requirements for LTC facilities with the decision finalized for acute inpatient hospitals and CAHs finalized in the FY 2025 inpatient PPS final rule. These commenters stated that the Federal standards for the collection of race and ethnicity are currently being revised, with a compliance deadline of October 2025 for Federal agencies to develop their plans to comply with these new standards and a deadline of March 2029 to come into full compliance. Commenters expressed concern that as these standards are being implemented, CMS could adopt a set of requirements that could swiftly change. A few commenters requested clarification on whether CMS is seeking to collect aggregate or patient-level data. Many commenters also stated that LTC facilities currently use MDS to collect information related to demographics and recommended not duplicating this data collection. These commenters did not support including race, ethnicity, and socioeconomic status in the respiratory virus reporting requirements because of concerns that this would increase the time needed for data collection and reporting.

Response: We thank commenters for the information and perspectives on the collection and submission of demographic data. While we are not expanding the collection of demographic data at this time due to the need to further refine this concept and the January 1, 2025, effective date of this reporting requirement, we acknowledge that not collecting this data would represent a gap in epidemiological information. We believe that demographic data plays an important role

[131] https://www.federalregister.gov/documents/2024/08/28/2024-17021/medicare-and-medicaid-programs-and-the-childrens-health-insurance-program-hospital-inpatient.

in informing healthcare decisions that ultimately impact the health and safety of residents. We intend to continue to explore ways to facilitate and strengthen the collection of additional demographic data in the future.

Comment: A commenter expressed concern that these proposed requirements were not proposed in the SNF PPS proposed rule. This commenter stated that HH PPS proposed rule is an inappropriate setting for LTC rulemaking and recommended that CMS only adopt policies that affect LTC facilities in rulemaking that applies to those facilities. This commenter also recommended adjusting payment rates for LTC facilities to accommodate the increased burden of reporting.

Response: We note that issues related to payment policy are outside the scope of the health and safety standards and LTC requirements for participation. We appreciate the concern that some commenters expressed regarding the use of the home health prospective payment rule as the CMS regulatory vehicle to notify the public of our proposal for LTC acute respiratory illness data reporting. It is typical practice for CMS to leverage differing regulatory vehicles to issue our regulatory priorities, especially as it relates to the issuance of policy updates for the Medicare health and safety standards. For example, the current post-PHE COVID-19 reporting requirements were issued on November 9, 2021, as part of the CY 2022 Home Health Prospective Payment System (PPS) final rule.[132] The importance of the reporting requirements coupled with the December 2024 expiration of the current post-PHE COVID-19 reporting requirements at §483.80 necessitated the use of this regulatory vehicle as a viable option to communicate this action. We encourage readers to regularly review OMB's Unified Agenda[133] and to sign up to receive email updates to get the latest information about your choice of CMS topics, but specifically timely information regarding activities and initiatives that may impact

[132] 86 FR 62240; https://www.federalregister.gov/documents/2021/11/09/2021-23993/medicare-and-medicaid-programs-cy-2022-home-health-prospective-payment-system-rate-update-home.
[133] https://www.reginfo.gov/public/do/eAgendaMain.

LTC facilities. Those interested can find a field at the bottom of CMS.gov to enter their email addresses and sign up for updates.[134]

Final Rule Action: We are finalizing our proposal to require ongoing respiratory illness reporting in a modified form as proposed. LTC facilities, in a standardized format and frequency specified by the Secretary, must electronically report information on acute respiratory illnesses, including influenza, SARS-CoV-2/COVID-19, and RSV, 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, confirmed resident cases, and hospitalized residents with confirmed cases.

b. 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,[135] a feedback loop between increased stress on hospitals, LTC facilities, illness in the community, and patient and resident health and safety. 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.[136,137] Specifically in LTC facilities, the significant adverse health impacts on residents caused by COVID-19 went far beyond the direct effects of COVD-19 morbidity and mortality.[138] Given the unprecedented impacts of, and learnings derived from, the COVID-19 PHE, we

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[134] https://www.cms.gov/.

[135] 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/).

[136] 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/).

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

[138] 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/).

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 proposed to require additional data reporting in the event of an acute respiratory illness PHE, or after the Secretary's determination that a significant threat of one exists.

Specifically, we proposed 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 invited comments on whether there should be limits to the data the Secretary can require without notice and comment rulemaking during a PHE, 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 sought 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 invited 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 invited 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?

Comment: Many commenters did not support adopting a policy which would allow the Secretary to require reporting without going through notice and comment rulemaking because this would deny an opportunity for those impacted by a rule to offer feedback and advocate for changes. Some commenters also expressed concern that changing requirements during a PHE could lead to unintentional non-compliance. A few commenters expressed concerns about the lack of any legal standard for a "significantly likely" PHE and stated that there is no statutory or other authority allows the Secretary to change mandatory reporting requirements based on a "significantly likely" PHE. These commenters stated that the term PHE has a specific meaning in statute and regulation, and the declaration of a PHE authorizes CMS to exercise significant flexibilities and powers intended to expedite the regulatory process. The commenters expressed concern regarding the precedent of CMS or any other Federal agency using such a vague categorization to circumvent the notice and comment rulemaking process. A commenter stated that the ability to waive notice and comment requirements only applies to voluntary information collections during a declared PHE and therefore, under the Paperwork Reduction Act (PRA) the Director of OMB would be required to review and approve any waiver of notice and comment rulemaking.

Response: We appreciate the responses regarding our proposal for reporting respiratory illness data during a PHE. We understand the need for clarity when PHE-related data reporting is required. At the time of a PHE declaration, clarification and guidance from the Secretary will occur so that LTC facilities will know what related data elements are activated for reporting. We expect to use a communication mechanism, such as a Quality Safety and Oversight Memo, that is readily available to the public, nationally accessible, and familiar to stakeholders, to ensure clarity and access to necessary information. Protecting residents during a PHE demands that we have better visibility and data on the spread and impact of an acute respiratory illness in the

nation's LTC facilities. A PHE declaration signals that focused and timely actions are needed so that responses are actionable and appropriate. The time it would take for a notice and comment period would delay the reporting and analysis of data and subsequent interventions that promote health and safety in facilities.

We recognize the concerns raised regarding the proposal to require increased PHE reporting in the likely event of a PHE. In response to the concerns raised we are withdrawing the proposal that the Secretary may require increased reporting in the event of a likely PHE. We encourage LTC facilities to use their required emergency preparedness plans and policies and procedures (§483.73) to promote readiness and actions that could reduce burden during a resource intense time (that is, during a PHE).

Comment: Many commenters expressed concern that changing reporting requirements during a PHE or an event significantly likely to become a PHE could lead to excessive administrative burden with limited benefits. Some of these commenters stated that daily reporting would take time away from resident care and infection control efforts. Some commenters stated that reporting data during the COVID-19 PHE did not lead to improved resources (such as distribution of PPE) but that it did lead to facilities being blamed for their challenges in addressing the pandemic. A commenter recommended considering supportive outreach to facilities, such as by QIOs, during future PHEs or events significantly likely to become a PHE.

Response: We thank the commenters for their concerns about increased data reporting during a PHE and the potential administrative burden with limited benefits. The best way targeted support can be provided during a PHE is to be aware of the what the facility needs. A data driven approach will ensure that LTC facilities, local and state health departments, CDC and HHS can identify trends so that mitigation strategies can be implemented quickly, and facilities can improve residents' health and safety and reduce the spread of illness. The CDC reduced reporting burden to facilities by streamlining reporting data entry forms, enhanced user support,

has implemented an improved helpdesk ticket response system and increased staffing and training for addressing NHSN user issues. The QIOs can monitor data in almost real time (both the streamlined weekly data and the expanded data requirements during a PHE) with minimal data lag to direct response efforts to outbreaks among nursing home residents. Some examples of interventions made during the COVID PHE include community pharmacy vaccine clinics, vaccine education tools, testing kits and ad campaigns.

Final Decision: We are finalizing as proposed our proposal to require additional reporting during a declared national, State, or local PHE for an acute infectious illness. We have withdrawn our proposal to require additional reporting if the Secretary determines that an event is "significantly likely" to become a PHE for an infectious disease. During a declared national, State, or local PHE for an acute infectious illness the Secretary may require reporting of data elements relevant to confirmed infections for staff, supply inventory shortages, staffing shortages, and relevant medical countermeasures and therapeutic inventories, usage, or both.

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). They address, among other things, requirements that providers and suppliers must meet to enroll in Medicare.

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 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 VII.B. of this final rule, we proposed a change to our existing Medicare provider enrollment regulations.

2. Legal Authorities

There are two principal categories of legal authorities for the Medicare provider enrollment provision addressed in section VII.B. of this final rule:

- 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. 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.) CMS' authority under section 1866(j)(3)(A) of the Act to impose a PPEO is not restricted to certain provider and supplier types (for example, hospices) but can apply to any provider or supplier type the Secretary determines appropriate.

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).[139] 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)

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

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.

For these and other reasons discussed in the proposed rule, we proposed 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 elected to address this issue via rulemaking in § 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 sub-regulatory guidance.

We received approximately 20 comments on our proposal. Summaries thereof and our responses are attached.

Comment: Several commenters supported our proposed change.

Response: We appreciate the commenters' support.

Comment: A commenter stated that 1 year of additional oversight is a reasonable timeframe for enhanced oversight but should not extend beyond that period unless there is reasonable evidence that non-compliance is occurring. Another commenter stated that CMS should outline in the final rule the methods it uses to determine the length of a PPEO.

Response: While we appreciate these comments, they do not directly pertain to the subject of our PPEO proposal, which is the expansion of the "new provider or supplier" definition to include reactivations. They instead involve the broader operational aspects of the overall PPEO process. Therefore, we respectfully believe they are outside the scope of this final rule.

Comment: Several commenters stated that CMS must furnish clear guidance to providers and suppliers under a PPEO concerning: (1) the PPEO's implementation and activities; (2) timelines for review; (3) appeals processes; (4) provider education; and (5) CMS' criteria for imposing sanctions and penalties.

Response: We appreciate these comments but respectively believe they are outside the scope of this final rule.

Comment: A commenter urged CMS to target any PPEO towards providers and suppliers engaging in egregious conduct rather than those furnishing services in good faith.

Response: We appreciate this comment but respectively believe it is outside the scope of this final rule.

Comment: A commenter recommended that PPEOs use pre-claim review for specific claim edits or targeted probe-and-educate audits to ensure that conditions of payment are met.

Response: We appreciate this comment but respectively believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS should go beyond the application of PPEOs and take further measures to address program integrity issues, especially among home health agencies (HHAs). This could include, for example, greater scrutiny of HHA owners, publication and auditing of ownership data, and closer monitoring of patient care.

Response: We appreciate this comment but respectively believe it is outside the scope of this final rule.

Comment: A commenter expressed concern that provider and supplier claims can be subject to multiple types of CMS reviews at the same time, such as Unified Program Integrity Contractor audits, Comprehensive Error Rate Testing reviews, and now PPEOs. The commenter believed that performing these reviews concurrently is unnecessary and places an undue burden on the affected provider or supplier. The commenter suggested that CMS cease these

simultaneous reviews and instead combine them into a single review or, if this is not possible, limit the scope and number of concurrent reviews.

Response: We appreciate this comment but respectively believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS should consider the deactivation reason in determining whether a reactivating provider or supplier should be subject to a PPEO. More specifically, the commenter recommended limiting PPEO application to reactivating providers and suppliers that were deactivated for a verifiable instance of non-compliance with enrollment requirements.

Response: We believe the commenter is referencing § 424.540(a)(4), which permits deactivation based on enrollment non-compliance. As we explained at length in the proposed rule, there are deactivation reasons other than § 424.540(a)(4) that involve provider or supplier non-compliance. These include all of the following:

- Failing to report a change to the provider's or supplier's enrollment information within the required timeframe (§ 424.540(a)(2)).
- Failing to timely respond to a revalidation request (§ 424.540(a)(3)).
- Having a non-operational or otherwise invalid practice location (§ 424.540(a)(5)).

Section 424.540(a)(1), meanwhile, permits deactivation if the provider or supplier has not billed Medicare for 6 or more consecutive months. A reactivation request after many months of billing inactivity could raise questions as to whether, for instance: (1) the provider or supplier will remain compliant with Medicare enrollment requirements once reactivated; or (2) another party has compromised the provider's or supplier's deactivated billing privileges and seeks to fraudulently bill Medicare via the latter's reactivated enrollment. Indeed, we noted in the proposed rule that we have identified these latter scenarios and believe that using a PPEO to closely monitor reactivated providers or suppliers that had been deactivated under § 424.540(a)(1) would help ensure program integrity.

The proposed rule also noted the deactivation reasons in § 424.540(a)(6) through (8). These are, respectively: (1) the provider or supplier is deceased; (2) the provider or supplier has voluntarily withdrawn from Medicare; and (3) the provider is the seller in an HHA ownership change under § 424.550(b). In each of these situations, the provider has departed the Medicare program, meaning the provider in effect is no longer compliant with Medicare enrollment requirements since it is not actively enrolled. If a provider that was deactivated under § 424.540(a)(7) or (8) is seeking to reenter the program, therefore, we must ensure the provider is not only compliant with Medicare enrollment requirements but also remains such during the period following its enrollment -- hence the importance of the PPEO. A requested reactivation of a provider that was deactivated under § 424.540(a)(6) raises particularly serious concerns, for the requesting party might be attempting to use the deceased provider's identity to enter and fraudulently bill Medicare.

In sum, we believe that each reactivation scenario, regardless of the underlying deactivation reason, requires thorough scrutiny of the reactivating provider via the PPEO.

Comment: A commenter stated that providers and suppliers that do not appear to be reactivating for inappropriate purposes (for example, fraud) should be exempt from a PPEO. The commenter believed this could include, for instance, providers and suppliers that had been deactivated for 6 consecutive months of Medicare non-billing or for failing to respond to a revalidation request.

Response: We previously explained that when a provider or supplier is reactivating its Medicare enrollment, it is, to some degree, reentering the Medicare program as would a new provider or supplier or one undergoing an ownership change. Given some of the similarities of these three transaction types in terms of CMS scrutiny and screening of their incoming CMS enrollment applications, we believe it is proper to apply a PPEO to all reactivating providers and suppliers irrespective of the deactivation reason. Moreover, part of the PPEO's purpose is to ensure that the reactivating provider or supplier is not reentering Medicare with nefarious

objectives. To the extent the commenter is suggesting we do so, we cannot automatically assume the provider or supplier has no intent to engage in fraud, waste, or abuse based solely on the reason for their deactivation. To illustrate, we have noted that a provider or supplier reactivating their enrollment after 6 consecutive months of non-billing may, in fact, be a party that has compromised that provider's or supplier's deactivated billing privileges. PPEO(s) help us confirm that this is not the case, and that the provider or supplier is legitimate and compliant. We thus respectfully decline the commenter's recommended exemption.

Comment: A commenter appeared to suggest that instead of applying a PPEO to reactivating providers and suppliers that were deactivated for enrollment non-compliance, CMS could instead require the reactivating provider or supplier to: (1) undergo CMS Medicare Learning Network (MLN)-based training; or (2) participate in a performance improvement plan (PIP).

Response: We respectfully disagree. In our view, neither of the commenter's recommended alternatives furnish the level of CMS scrutiny that a PPEO provides. For example, they would not involve a detailed CMS review of claim accuracy or billing patterns, actions that are possible under a PPEO and help ensure that a reactivated provider or supplier is not engaging in fraud, waste, or abuse. Indeed, preventing such conduct and facilitating program integrity are the central purposes of a PPEO, and we do not believe that training and PIPs, though useful, can by themselves sufficiently fulfill these aims.

After considering the comments we received, we are finalizing our proposed change to § 424.527(a)(4) without modification.

VIII. Collection of Information Requirements

A. Statutory Requirement for the 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 2025 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 rule, we proposed to collect four additional items as standardized patient assessment data elements and modified 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 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 assumed the Food Runs Out and Food Doesn't Last data elements require 0.15 minutes each of clinician time to complete. We assumed 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 rule, CMS also proposed 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 provision 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 provisions 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 28.

TABLE 28: 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 28 0.7714×82.76+0.2216×95.98+0.007×89.26= 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 29 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 30 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 29. 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 29 are used to calculate the hourly burden estimates in table 30 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 x (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 x 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 x (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 x 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 x (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 x 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 x (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 x 1,184,618 ROC assessments = 56,861,664

minutes/60 minutes = 947,694 hours for all HHAs

Table 30 summarizes the estimated clinician hourly burden for the OASIS that will be implemented in 2027 with the 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 calculated the 2025 and 2027 burden estimate in minutes and then calculated an hourly burden shown in table 30. 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 30. 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 31 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 31 by the weighted clinician average hourly wage of $85.74. We then calculated 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 estimated an increase in clinician costs $12,604,894.62 between 2027 and 2025 related to the implementation of the proposals outlined in this 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 31. 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

Comment: Commenters that supported the proposal expressed concerns about implementation including that the vendors be provided enough time to prepare for the changes, that home health agencies be provided time and resources to educate staff on the changes, that OASIS revisions are too frequent and burdensome for agencies and that implementation of the proposal would be burdensome. Some commenters cautioned that SDOH needs identified must be addressed, and one suggested that CMS should provide additional reimbursement to HHAs for the follow-up required to address identified needs.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. We proposed the SDOH data elements in the CY 2025 HH PPS proposed rule with an effective date to begin collection via the OASIS instrument of January 1, 2027, to ensure that vendors and HHAs have sufficient time to prepare for implementation. We will make training available to HHAs on the changes to the OASIS, consistent with education and training resources for previous revisions to the OASIS instrument. We acknowledge that revisions to the OASIS require time and effort and resources for providers to prepare for the changes and we are committed to proposing revisions to the OASIS no more frequently than every 2 years. We agree that patients' needs should be addressed by the HHA, consistent with applicable rules and regulations, although we note that the proposal does not specify a requirement for how HHAs may address patients' needs.

Comment: Commenters that did not support the proposal acknowledged that SDOH information is important but adding four data elements to the OASIS and modifying a fifth would be burdensome. A commenter noted that revisions to the OASIS are too frequent and recommended that CMS limit revisions to intervals of no less than 4 years. Another commenter suggested that the proposed living situation data element is duplicative of information that is

already collected and recommended that the look-back for the utilities data element be changed from 12 months to three to capture more reliable, valid, and timely information. Another commenter encouraged CMS to consider using SDOH information as part of the risk-adjusted outcome quality measures. A commenter stated the proposal is not aligned with health-related social needs reporting requirements across the care continuum and that further testing and refinement are needed to ensure the proposed items work as intended in this setting. This commenter noted that CMS' evaluation of the AHC HRNS screening tool in the AHC Model showed that screening did not appear to increase beneficiary connection to community resources or health-related social need resolution, and they recommended CMS conduct further testing and developing clearer implementation guidance before adopting the proposed data elements in the HHQRP.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. As previously stated, we acknowledge that revisions to the OASIS require time and effort and resources for providers to prepare for the changes and we are committed to proposing revisions to the OASIS no more frequently than every 2 years. We disagree that the proposed Living Situation data element is duplicative of information that is already collected because it addresses housing insecurity, which is not part of the information captured in the current OASIS. We believe that the proposed data elements are not setting-specific, and that the testing conducted in their development has been sufficiently rigorous that we can adopt the data elements into the OASIS and the other PAC instruments with confidence.

After consideration of the public comments received, we are finalizing our proposal 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.C.D. of this rule beginning January 1, 2027, with the CY 2027 HH QRP.

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 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 VI.A. of the rule, we discussed 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 proposed 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 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 estimated there are

9,565 Medicare-certified HHAs and that the 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 and $3,078,400 for all HHA's. We also estimated 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 $7.00 per HHA for all HHAs to fulfill this requirement.

In addition, we estimated that the proposed 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, or $99,763 for all HHA's to fulfill the requirement. We also proposed that 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 or $33,286 for all HHA's to fulfill this requirement.

TABLE 32: 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

Comment: A few commenters stated that CMS did not adequately account for the burden of the proposed acceptance-to-service policy in their estimates for compliance that maintaining the proposed policy would take HHAs appreciably more than 5 minutes per year and that the amount that CMS estimated ($9,000 to implement and $30,000 to maintain) would be insurmountable for small agencies. Likewise, a commenter stated that the estimate of $99,763 as

a one-time cost for making the information public equates to approximately $9.07 per HHA which is less than the commenter believes this activity will cost. Other commenters stated that they did not support the proposed acceptance-to-service policy because of concerns that data collection and reporting for such a policy will create additional administrative burden for HHAs.

Response: We appreciate the commenters feedback on burden estimates for the development of the proposed acceptance-to-service policy and the requirement to make this information public and update annually. We agree with the commenters feedback and have made adjustments to the burden estimates.

To develop the acceptance-to-service policy, we expect the HHA to utilize a physician and nurse to create and update the HHA's policies. We estimated there are 9,565 Medicare-certified HHAs and that the proposed new requirement would take 2 hours 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 $643.68 per HHA ($82.76 x 2 + $239.08 x 2) and $6,156,799 for all HHA's ($1,583,199+ $4,573,600). We also estimated the HHA nurse would review the acceptance-to-service policy on an annual basis. This annual review would take 30 minutes for an HHA nurse at a cost of $41.38 per HHA ($82.76 x 30/60 minutes) and $395,799.70 for all HHA's ($41.38 x 9,565) to fulfill this requirement.

In addition, we estimated that the proposed requirement to make the specified information public would take an HHA 30 minutes on a one-time basis at a cost of $20.85 per HHA or $199,430.25 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 $20.85 per HHA ($41.70 hour x 30/60 minutes) or $199,430.25 for all HHA's ($20.85 x 9,565) to fulfill the requirement. We also proposed that the HHA administrative professional would review information to ensure accuracy as frequently as the services change. We revised the requirement at § 484.105(i)(2) to require HHAs to review public information regarding services offered, service limitations, or service frequency as frequently as

the services as changed, but no less often than annually. Therefore, we estimate the average HHA may need to update this service information as frequently as 4 to 6 times per year, but no less than annually to assure the continued accuracy of the posted information. We estimate this review will take 10 minutes per review with an estimated six reviews annually at a cost of $41.70 for an HHA ($41.70 x 10/60 minute= $6.95 x 6=$41.70) or $398,860.50 for all HHA's (41.70 x 9,565= $398,860.50) to fulfill this requirement.

TABLE 33: 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
$643.68(one time cost)	9,565	$6,156,799
$41.38 (annually)	9,565	$395,800
$20.85 (one time cost)	9,565	$199,430
$6.95 (per review)	9,565	$66,476
$41.70 (6 reviews)	9,565	$398,860

After consideration of the public comments we received, we are modifying the final burden estimated for home health agencies to be in compliance with the acceptance-to-service policy.

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. Some of these procedures have been codified in § 424.527. As explained in section VII. of this rule, we proposed to expand the definition of "new provider or supplier" in § 424.527(a) (solely for purposes of applying a provisional period of enhanced oversight) to include providers and suppliers that are reactivating their Medicare enrollment and billing privileges under § 424.540(b). We stated in the proposed rule that we do

not anticipate any ICR burden associated with this provision, for we are merely expanding an existing regulatory definition.

We did not receive any comments on our ICR estimates and are therefore finalizing them as proposed.

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

In section VII.B. of this rule we discussed the final policy related to LTC requirements for acute respiratory illness reporting. At §483.80(g)(1)(i) through (ix) and (g)(2), we proposed 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 proposed that the data elements for required reporting would 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 proposed that LTC facilities would continue to report these data on a weekly basis through a format specified by the Secretary and specifically noted that we intend to continue reporting through the CDC's NHSN. We indicated that 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.

In addition, during a declared national, State, or local PHE for an acute infectious illness we also proposed 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, staffing shortages, and relevant medical countermeasures and therapeutics inventories, usage, or both.

We noted that 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 proposals. We estimated 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 the 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 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 x 2= $90.84 (rounded to $91). According to CMS, there are currently 14,926 LTC facilities as of April 2024.[140]

Based on this salary information and facility data, we estimated 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 x 14,926 facilities) at a cost of $2,716,532 (29,852 x $91) or $182 ($91 x 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 (Reform of Requirements for

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

Long-Term Care Facilities (CMS-10573)) estimates a total burden cost of $55,972,800 (1 hour x 52 weeks x $69 (IP 2022 salary) x 15,600 LTC facilities as of 2022) based on weekly reporting. We expect that ongoing reporting will require continuous efforts to collect and organize the information necessary to report the data through the NHSN or other system as determined by the Secretary. 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 acknowledged 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 included two burden estimates to cover a range in the 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 estimated that total annual burden hours for all LTC facilities to comply would be 776,152 hours (1 hour x 52 weeks x 14,926 facilities) at a cost of $70,629,832 (776,152 total hours x $91) or $4,732 ($91 x 1 hour x 52 weeks) per facility annually.

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

In summary, we estimated a total annual burden for all LTC facilities for the proposed ICRs of 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 facility annually. The ICR burden currently associated with §483.80(g) is included under OMB control number 0938-1363; expiration date: April 30, 2026. We will submit the revised information collection request to include these preliminary estimates to OMB for approval under OMB control number 0938-1363 (CMS-10914). We note that any additional ICR burden related to the specific instruments used for reporting and the time necessary to submit/report the data is the National Healthcare Safety Network (NHSN) Surveillance in Healthcare Facilities (OMB control number 0920-1317) package.

TABLE 34: 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 welcomed public comments on our ICR burden estimates, and on ways that reporting burden can be minimized while still providing adequate data. We also welcomed 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 welcomed comments that address system readiness and capacity to collect and report these data.

Comment: A commenter did not agree with the assumptions used for estimating the burden of the proposed LTC respiratory illness data reporting requirements. This commenter stated that CMS has underestimated the required time for reporting these data and underestimated the cost by assuming that the activity would be completed by an RN. The commenter stated that this data collection is often done by the IP, the Director of Nursing, or the Nursing Home Administrator, all of whom have higher wage rates than an RN. The commenter noted that the BLS May 2023 National Industry-Specific Occupational Employment and Wage

Estimates website, estimates the median hourly wage for a Nursing Home Administrator at $58.82, which raises the cost estimates by almost 50 percent as compared to the hourly wage used by CMS. The commenter also notes that the burden estimates do not account for other staff that may be involved in supporting the IP, the DON, or the Administrator in the data collection. Furthermore, they note that the time to gather and report the data to NHSN is impacted by facility size, number of weekly admissions and discharges, and the outbreak status of the facility. As an example, the commenter shares that a facility with an average census of 57 residents requires 3 hours per week to report to NHSN and a facility with an average census of 76 residents requires 5 hours per week to report to NHSN. They note that these estimates are based on the time currently necessary to comply with the existing COVID-19 data reporting requirements and asserts that the proposed revisions would increase this time based on the expanded data reporting elements. This commenter recommended that CMS not finalize the proposed rule.

Response: We appreciate the feedback shared by this commenter regarding the effort and time currently exercised by varying facilities to comply with the existing COVID-19 data reporting requirements. We disagree with the commenter's assertion that the proposed revisions would increase burden and believe that the streamlined data elements proposed will positively impact data collection and reporting efforts, despite the possibility for changes in the frequency of reporting. The proposal reduced the number of data elements required for ongoing reporting from the current post-COVID-19 PHE reporting requirements set to expire December 2024. Specifically, starting on September 30, 2024, NHSN will have a single reporting form for all nursing home respiratory illness and vaccination data reporting, combining four forms into one, and resulting in a significant reporting burden reduction. Several data elements were removed, so even with the addition of influenza and RSV reporting, this single reporting form and new requirements result in a reduction in the number of data fields by 34 (from 50), and an overall

time and burden reduction. In summary, the changes from the current post-PHE COVID-19 reporting to the proposals finalized in this rule include removing--

- Staff Pathway (including positive tests among staff)
- Staff COVID-19 vaccination (-20 required fields)
- Total resident deaths
- Resident COVID-19 deaths
- Total beds
- Resident census
- Resident medical contraindications, declinations, and other/unknown vaccination statuses.

Under the current forms there are 50 total fields (33 vaccination, 17 Pathways) and under the proposed CoP and revised forms there are 16 total fields (includes the addition of influenza and RSV).

In the proposed rule, we provided an explanation of the salary data used to inform our estimates. These requirements are a part of a facility's responsibility to develop and maintain an infection control program and as such, we based on our estimate on the assumption that the main individual conducting these activities would be the IP. Furthermore, to support the estimate we used the national mean salary data for an RN and increased the salary by 100 percent to account for overhead costs and fringe benefits. We acknowledge the commenter's feedback noting that varying staff types, besides the IP, may be responsible for completing the activities necessary to comply with the respiratory illness data reporting requirements. However, as the commenter noted, the IP is likely one of the individuals that may conduct the activities and therefore since we cannot know how often a DON or the administrator may be involved, we believe our assumption to estimate costs based on the IP, who is a RN, is reasonable. We also note that additional burden related to the specific instruments used for reporting and the time necessary to submit/report the data to the NHSN is account for in the NHSN Surveillance in Healthcare Facilities (OMB control number 0920-1317) package. This package accounts for additional

burden related to the IP completing the data entry either manually (25 minutes) or by uploading a CSV file (20 minutes) in NHSN. Together, we believe that the burden associated for complying with the respiratory illness data reporting requirements has been reasonability estimated.

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 invited public comments on these potential information collection requirements. We received public comment on the 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 final rule, we summarized comments that we received on a RFI related to the future measure concepts for the expanded HHVBP Model. The proposed rule also included an update on potential future approaches for integrating health equity that are being considered for the expanded HHVBP Model. This final rule does not make any changes to the expanded HHVBP Model.

4. Home IVIG Items and Services

Division FF, section 4134 of the CAA, 2023 (Pub. L. 117-328), which amended section 1842(o) of the Act, 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. Section 1834(j)(5) of the Act clarifies that a supplier who furnishes these services meet the requirements of a supplier of medical equipment and supplies. The permanent, bundled home IVIG items and services payment is updated by the home health update percentage beginning

January 1, 2025.

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 states that this is specifically limited to Medicare beneficiaries. As explained in section VI.A. of this rule, we are proposed 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 proposed that HHAs would be required to make specified information about their services and service limitations available to the public.

We received no comments on regulatory impact analysis for the proposal and believe there are no additional costs beyond what we have recognized in the collection of information section.

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. Some of these procedures have been codified in 42 CFR 424.527. As explained in section VII. of this rule, we proposed 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 proposed streamlined weekly data reporting requirements for certain respiratory illnesses. We are also proposed additional, related data elements that could be activated in the event of a future acute respiratory illness PHE.

We did not receive any comments specifically related to the regulatory impact analysis for these proposed requirements. Comments received on these proposals, including those related to our ICR burden estimates and general burden concerns, can be found earlier in the rule in the Collection of Information section.

B. Overall Impact

We have examined the impacts of this final 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.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB'S Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a regulatory impact analysis that presents the costs and benefits of the rulemaking to the best of our ability. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has determined that this rule meets the criteria set forth in 5U.S.C.804(2). Therefore, OMB has reviewed this final rule and the Department has provided the following assessment of their impact.

C. Detailed Economic Analysis

1. Effects of the Final Policy Changes for the CY 2025 HH PPS

This rule updates 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 $85 million (0.5 percent). The $85 million increase in estimated payments for CY 2025 reflects the effects of the final CY 2025 home health payment update percentage of 2.7 percent ($460 million increase), an estimated 1.8 percent decrease that reflects the effects of the permanent adjustment ($305 million decrease), and an estimated 0.4 percent decrease that reflects the effects of an updated FDL ($70 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 35 represents how HHA revenues are likely to be affected by the final 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 35 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 final -1.975 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 final update to the LUPA add-on factors. The seventh column shows the payment effects of the final 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 final provisions.

Overall, it is projected that aggregate payments in CY 2025 would increase by 0.5 percent which reflects the 1.8 percent decrease from the permanent adjustment, the 2.7 payment update percentage increase, and the 0.4 percent decrease from increasing the FDL. As illustrated in table 35, 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.

TABLE 35: CY 2025 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	CY 2025 Permanent BA Adjustment	CY 2025 Case-Mix Weights Recalibration Neutrality Factor	CY 2025 Updated Wage Index (with 5% cap and OMB delineations)	CY2025 LUPA Add-On Factors Update	CY 2025 Final HH Payment Update Percentage	CY 2025 Fixed-Dollar Loss (FDL) Update	Total
All Agencies	**9,638**	**-1.8%**	**0.0%**	**0.0%**	**0.0%**	**2.7%**	**-0.4%**	**0.5%**
Facility Type and Control								
Free-Standing/Other Vol/NP	866	-1.7%	0.0%	-0.6%	0.0%	2.7%	-0.5%	-0.1%
Free-Standing/Other Proprietary	7,049	-1.8%	0.0%	0.2%	0.0%	2.7%	-0.4%	0.7%
Free-Standing/Other Government	149	-1.7%	0.0%	0.6%	0.0%	2.7%	-0.5%	1.1%
Facility-Based Vol/NP	429	-1.7%	-0.1%	-0.3%	0.0%	2.7%	-0.6%	0.0%
Facility-Based Proprietary	44	-1.8%	0.1%	0.6%	0.0%	2.7%	-0.4%	1.2%
Facility-Based Government	137	-1.7%	0.0%	0.6%	0.0%	2.7%	-0.5%	1.1%
Subtotal: Freestanding	8,064	-1.8%	0.0%	0.1%	0.0%	2.7%	-0.4%	0.6%
Subtotal: Facility-based	610	-1.7%	-0.1%	-0.2%	0.0%	2.7%	-0.6%	0.1%
Subtotal: Vol/NP	1,295	-1.7%	0.0%	-0.5%	0.0%	2.7%	-0.5%	0.0%
Subtotal: Proprietary	7,093	-1.8%	0.0%	0.2%	0.0%	2.7%	-0.4%	0.7%
Subtotal: Government	286	-1.7%	0.0%	0.6%	0.0%	2.7%	-0.5%	1.1%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	205	-1.7%	0.1%	0.7%	0.0%	2.7%	-0.5%	1.3%
Free-Standing/Other Proprietary	731	-1.8%	0.3%	1.5%	0.0%	2.7%	-0.3%	2.4%
Free-Standing/Other Government	101	-1.7%	0.2%	1.2%	0.0%	2.7%	-0.6%	1.8%
Facility-Based Vol/NP	187	-1.6%	0.1%	0.9%	0.0%	2.7%	-0.7%	1.4%
Facility-Based Proprietary	14	-1.8%	0.5%	-0.5%	0.0%	2.7%	-0.3%	0.6%
Facility-Based Government	100	-1.7%	0.1%	0.3%	0.0%	2.7%	-0.6%	0.8%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	661	-1.7%	0.0%	-0.7%	0.0%	2.7%	-0.5%	-0.2%
Free-Standing/Other Proprietary	6,310	-1.8%	0.0%	0.1%	0.0%	2.7%	-0.4%	0.6%
Free-Standing/Other Government	48	-1.8%	-0.1%	0.0%	0.0%	2.7%	-0.4%	0.4%
Facility-Based Vol/NP	242	-1.7%	-0.1%	-0.6%	0.0%	2.7%	-0.6%	-0.3%
Facility-Based Proprietary	30	-1.8%	0.0%	0.9%	0.0%	2.7%	-0.5%	1.3%
Facility-Based Government	37	-1.7%	-0.1%	0.8%	0.0%	2.7%	-0.4%	1.3%
Facility Location: Urban or Rural								
Rural	1,338	-1.8%	0.2%	1.3%	0.0%	2.7%	-0.4%	2.0%

Urban	7,328	-1.8%	0.0%	-0.1%	0.0%	2.7%	-0.4%	0.4%
Facility Location: Region of the Country (Census Region)								
New England	300	-1.7%	-0.1%	-1.6%	0.0%	2.7%	-0.5%	-1.2%
Mid Atlantic	379	-1.7%	-0.1%	-1.4%	0.0%	2.7%	-0.4%	-0.9%
East North Central	1,427	-1.8%	0.0%	0.1%	0.0%	2.7%	-0.4%	0.6%
West North Central	569	-1.7%	-0.1%	0.7%	0.0%	2.7%	-0.5%	1.1%
South Atlantic	1,566	-1.8%	-0.1%	1.3%	0.0%	2.7%	-0.4%	1.7%
East South Central	357	-1.8%	0.2%	2.4%	0.0%	2.7%	-0.3%	3.2%
West South Central	1,996	-1.8%	0.2%	1.2%	0.0%	2.7%	-0.4%	1.9%
Mountain	705	-1.7%	-0.1%	1.2%	0.0%	2.7%	-0.5%	1.6%
Pacific	2,296	-1.8%	0.0%	-2.0%	0.0%	2.7%	-0.4%	-1.5%
Outlying	43	-1.8%	0.5%	-1.2%	0.0%	2.7%	-0.4%	-0.2%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,178	-1.8%	0.1%	0.0%	0.0%	2.7%	-0.5%	0.5%
100 to 249	1,504	-1.7%	0.0%	-0.4%	0.0%	2.7%	-0.5%	0.1%
250 to 499	1,702	-1.8%	0.0%	-0.2%	0.0%	2.7%	-0.5%	0.2%
500 to 999	1,909	-1.8%	0.0%	0.0%	0.0%	2.7%	-0.4%	0.5%
1,000 or More	2,345	-1.8%	0.0%	0.0%	0.0%	2.7%	-0.4%	0.5%

Source: CY 2023 Medicare claims data for periods with matched OASIS records ending in CY2023 (as of July 11, 2024).

Notes: The estimated 1.8 percent decrease related to the finalized permanent adjustment includes all payments, while the -1.975 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 “CY 2025 Updated Wage Index (with 5% cap and OMB delineations)” column reflects updated hospital wage index data (reflecting 2022 cost report data) with the revised OMB delineations from OMB Bulletin No. 23-01 and a 5-percent cap on wage index decreases. The “CY 2025 LUPA Add-On Factors Update” column has an overall impact of -0.02 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 0.35. 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 9,638): totals involving facility type or control only add up to 8,674 and totals involving urban/rural locations only add up to 8,666.

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 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.

We proposed to collect four additional 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. The four assessment items proposed for collection were (1) Living Situation;(2) Food Runs Out; (3) Food Doesn't Last; and (4) Utilities. We also proposed to modify the current Access to Transportation item with a revised Transportation (Access to Transportation) item beginning with the CY 2027 HH QRP. CMS also proposed 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 was 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 rule provides a detailed description of the net increase in burden 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 $12,604,89 5 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 rule. In summary, the implementation of proposed provisions outlined in this rule for the HH QRP is estimated to increase the burden on HHAs by $1,059 per HHA annually, or $12,604,895 for all HHAs annually.

Commenters that supported the proposal expressed concerns about implementation including that the vendors be provided enough time to prepare for the changes, that home health agencies be provided time and resources to educate staff on the changes, that OASIS revisions are too frequent and burdensome for agencies and that implementation of the proposal would be burdensome. Some commenters cautioned that SDOH needs identified must be addressed, and one suggested that CMS should provide additional reimbursement to HHAs for the follow-up required to address identified needs.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. We proposed the SDOH data elements in the CY 2025 HH PPS proposed rule with an effective date to begin collection via the OASIS instrument of January 1, 2027, to ensure that vendors and HHAs have sufficient time to prepare for implementation. We will make training available to HHAs on the changes to the OASIS, consistent with education and training resources for previous revisions to the OASIS instrument. We acknowledge that revisions to the OASIS require time and effort and resources for providers to prepare for the changes and is committed to proposing revisions to the OASIS no more frequently than every 2 years. We agree that patients' needs should be addressed by the HHA, consistent with applicable rules and regulations, although we note that the proposal does not specify a requirement for how HHAs may address patients' needs.

Comment: Commenters that did not support the proposal acknowledged that SDOH information is important but adding four data elements to the OASIS and modifying a fifth would be burdensome. A commenter noted that revisions to the OASIS are too frequent and recommended that CMS limit revisions to intervals of no less than four years. A commenter suggested that the proposed living situation data element is duplicative of information that is

already collected and recommended that the look-back for the utilities data element be changed from 12 months to 3 months to capture more reliable, valid, and timely information. Another commenter encouraged CMS to consider using SDOH information as part of the risk-adjusted outcome quality measures. A commenter stated the proposal is not aligned with health-related social needs reporting requirements across the care continuum and that further testing and refinement are needed to ensure the proposed items work as intended in this setting. This commenter noted that CMS' evaluation of the AHC HRSN screening tool in the AHC Model showed that screening did not appear to increase beneficiary connection to community resources or health-related social need resolution, and they recommended CMS conduct further testing and developing clearer implementation guidance before adopting the proposed data elements in the HHQRP.

Response: We acknowledge the commenters' concerns and appreciate their suggestions. As previously stated, we acknowledge that revisions to the OASIS require time and effort and resources for providers to prepare for the changes and we are committed to proposing revisions to the OASIS no more frequently than every 2 years. We disagree that the proposed Living Situation data element is duplicative of information that is already collected because it addresses housing insecurity, which is not part of the information captured in the current OASIS. We believe that the proposed data elements are not setting-specific, and that the testing conducted in their development has been sufficiently rigorous that we can adopt the data elements into the OASIS and the other PAC instruments with confidence.

After consideration of the public comments we received, we are finalizing our proposal 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 rule beginning January 1, 2027, with the CY 2027 HH QRP.

3. Effects of the Expanded HH VBP Model

There were no proposed changes to the expanded HHVBP Model for CY 2025. Therefore, we assumed there are no impacts resulting from this provision. 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 the proposed rule, will be summarized in this 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 final rule as added by section 4134 of the CAA, 2023 and accordingly, describes the impact for CY 2025 only. Table 36 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 final CY 2025 home IVIG items and services rate. The fifth column estimates the total cost to Medicare for CY 2025 ($9,535,238). The increase in estimated costs of covered IVIG items and services for CY 2025 relative to the baseline year in CY 2024 (using updated CY 2023 claims data as of July 26, 2024) is $250,000. Table 36 represents the estimated impacts of the home IVIG items and services payment for CY 2025 by census region.

TABLE 36: ESTIMATED COSTS OF COVERED IVIG ITEMS AND SERVICES, CY 2025

Year	Number of Active Enrollees[1]	Number of IVIG Visits[1]	Final Nationwide Rate	Estimated Cost
CY 2025	1,938	22,081	$431.83	$9,535,238

[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 July 26, 2024.

TABLE 37: 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	2,291	$989,323
Middle Atlantic	NJ, NY, PA	220	2,625	$1,133,554
South Atlantic	DE, DC, FL, GA, MD, NC, SC, VA, WV	505	5,254	$2,268,835
East North Central	IL, IN, MI, OH, WI	161	1,815	$783,771
East South Central	AL, KY, MS, TN	192	2,064	$891,297
West North Central	IA, KS, MN, MO, NE, ND, SD	136	1,597	$689,633
West South Central	AR, LA, OK, TX	198	2,177	$940,094
Mountain	AZ, CO, ID, MT, NV, NM, UT, WY	148	1,704	$735,838
Pacific	AK, CA, HI, OR, WA	214	2,554	$1,102,894
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 July 26, 2024. Each IVIG claims is assigned to a single census division. There are eleven 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 proposed to add a new standard § 484.105(i), which sets forth a requirement for HHAs to establish an acceptance-to-service policy. All costs associated with this policy are located in the section VIII. of this final rule (Collection of Information). There are no transfers associated with this requirement.

6. Provider Enrollment Provisions

For purposes of applying a PPEO, we proposed 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). We stated in the proposed rule's regulatory impact section that we were 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 could formulate a burden projection. Second, we could not predict the scope, extent, and length of any future PPEO or the provider or supplier type(s) to which it may apply. Accordingly, we solicited public comment from stakeholders on the potential burden of our expansion of § 424.527(a).

We did not received comments regarding the potential impact of § 424.527(a)'s

expansion and are therefore finalizing our assessments as discussed in the previous paragraph.

7. Effects of the LTC Requirements for Acute Respiratory Illness Reporting

We proposed 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 final rule (Collection of Information). There are no transfers associated with this requirement. We welcomed public comments on our estimates, and on ways that reporting burden can be minimized while still providing adequate data. We also welcomed 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 welcomed comments that address system readiness and capacity to collect and report these data.

A summary of comments received on the proposed rule can be found in sections VI.B. (Long-Term Care (LTC) Requirements for Acute Respiratory Illness Reporting) and section VIII.B.5. (Collection of Information) of this final rule.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with the 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 this year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed 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 commenters would be a fair estimate of the number of reviewers of this rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer

reads approximately 50 percent of the rule. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $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 3.49 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $371.41 (3.49 hours × $106.42). Therefore, we estimate that the total cost of reviewing this regulation is $399,637 ($371.41 × 1,076) [1,076 is the number of estimated reviewers, which is based on the total number of unique commenters from this year's proposed rule].

E. Alternatives Considered

1. HH PPS

For the CY 2025 HH PPS, we considered alternatives to the final provisions articulated in section II.C. of this rule. As described in section II.C.1.b. of this rule, we finalized a mapping of three OASIS items (therapies, vision, and pain) and a lookback period of 12 months 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 mapping the three items (therapies, vision, and pain). Alternatives to the lookback period consisted of our initial proposal of 24 months and a shorter, three-month lookback period. We also considered no lookback period. However, to continue with the previously finalized methodology for assessing behavior changes, which uses certain OASIS items, we finalized the OASIS-E to OASIS-D mapping of the three items and a 12-month lookback period.

As described in section II.C.1.g. of this 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 -1.975 percent permanent adjustment, as finalized in this rule, included taking the full adjustment of -

3.95 percent. Another alternative would be to take the remaining permanent adjustment not taken in the CY 2024 HH PPS final rule, which resulted in -2.890 percent. 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 are not taking the -3.95 adjustment as we wish to be responsive to commenter concerns about the on-going permanent adjustments to payment rate. Additionally, we believe that applying the permanent behavior adjustment calculated using CY 2023 claims over a period of several years, or delaying the permanent adjustment, would not be appropriate as it would further impact budget neutrality and likely lead to a compounding effect creating the need for a larger permanent reduction to the payment rate in future years. Therefore, we are finalizing a -1.975 percent (half of the permanent -3.95 percent adjustment) permanent adjustment to the CY 2025 30-day payment rate. As stated previously in this final rule, we did not propose implementing the temporary adjustment to reconcile retrospective overpayments in CYs 2020, 2021, 2022, and 2023.

Finally, we considered not finalizing adopting the revised 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. We continue to 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.

2. Home IVIG Items and Services

For the CY 2025 HH PPS, we did not consider alternatives to updating 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, and to annually update this rate.

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 38, we have prepared an accounting statement showing the classification of the transfers and benefits associated with the CY 2025 HH PPS provisions of this final rule.

TABLE 38: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS, FROM CY 2024 TO CY 2025

Category	Transfers
Annualized Monetized Transfers	$85 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 39, 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 39: 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	$12,604,895 (2% Discount Rate)

We received no comments on the proposal and therefore are finalizing this provision without modification.

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 40, we have prepared an

accounting statement showing the classification of the transfers and benefits associated with the CY 2025 IVIG provisions of this final rule.

TABLE 40: ACCOUNTING STATEMENT: IVIG CLASSIFICATION OF ESTIMATED TRANSFERS AND BENEFITS CY 2025

Category	Transfers
Annualized Monetized Transfers	$250,000
Bearers of Transfer Gain	Medicare DMEPOS suppliers

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[141] and approximately 96 percent of HHAs are considered small entities. Table 41 shows the number of firms, revenue, and estimated impact per home health care service category.

TABLE 41: 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

[141] https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx.

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	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'' on a "substantial" number of small entities 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. We detail the CY 2025 HHA impacts by facility type and area of the country in table 35. Specifically, we estimate that the net impact of the policies in this final rule will only have a significant impact on HHAs in the East South Central Region, which is reflected in the last column in table 35 as a 3.2 percent increase in revenue when comparing CY 2025 payments to estimated CY 2024 payments. The East South Central represents 3.7 percent (357 of 9638) of the number of HHAs. HHAs in all other regions will experience net impacts ranging from -1.5 percent (Pacific Region) to 1.9 percent (West South Central). Furthermore, in section IX.E. of this final rule (Alternatives Considered), we provide a detailed analysis of the alternatives considered for the various provisions in this final rule. As a result, based on our analysis, we conclude that the provisions in this final rule will not 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 certifies that this final rule will not have significant economic impact on a substantial number of small entities. We received no comments on the overall RFA analysis.

This RFA section along with the RIA constitutes our final regulatory flexibility analysis.

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 604 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 final rule is not applicable to hospitals. Therefore, the Secretary has certified that this final 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 rule will 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 final 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 estimated that the provisions in this rule will result in an estimated net increase in home health payments of 0.5 percent for CY 2025 ($85 million). The $85 million increase in estimated payments for CY 2025 reflects the effects of the final CY 2025 home health payment update percentage increase of 2.7 percent ($460 million increase), a 0.4 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 ($70 million decrease), and an estimated 1.8 percent decrease in payments that reflects the effects of the permanent behavior adjustment ($305 million decrease). In addition, the estimated impact of the home IVIG items and services payment for CY 2025 is an increase of $250,000.

K. Waiver Fiscal Responsibility Act Requirements

The Director of OMB has waived the requirements of section 263 of the Fiscal Responsibility Act of 2023 (Pub. L. 118-5) pursuant to sections 265(a)(1) and (a)(2) of Public Law 118-5.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 17, 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 amends 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, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)/coronavirus 2019 (COVID-19), and respiratory syncytial virus (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, 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)(i) 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.

(ii) Review the information specified in paragraph (i)(2)(i) of this section as frequently as the services are changed, but no less often than annually.

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Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2024-25441 Filed: 11/1/2024 4:15 pm; Publication Date: 11/7/2024]